



06-30-03

6/1/1636

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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JUL 03 2003

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In re Application of: Stephen J. Elledge et al.

Serial No.: 09/122,384

Filed: July 24, 1998

For: Rapid Subcloning Using Site-Specific  
Recombination

Group Art Unit: 1636

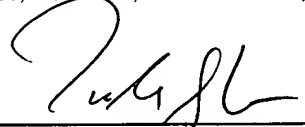
Examiner: James Ketter

Atty. Dkt. No.: BAY136/4-10CIP/36000

CERTIFICATE EXPRESS MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail Label No. EV238368807 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below:

June 27, 2003  
Date

  
Timothy S. Corder

WRITTEN RECORD OF TELEPHONIC INTERVIEWS

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicant's representative has had series of telephone communications with the Examiner regarding the litigation in which Assignee of the above-captioned application is a party.

Specifically, two such lawsuits were discussed with the Examiner:

- (1) a State Court litigation relating to breach of contract and misappropriation/theft of trade secrets including issues that involve materials described and claimed in the present patent application. This litigation is CAUSE



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NO. 2001-61352, Baylor College of Medicine and BCM Technologies v. Clontech Labs, Inc. District Court, Harris County Texas, 133<sup>rd</sup> Judicial District (the "State Action"); and

(2) a Declaratory Judgment Action that was filed in the U.S. District Court for the Southern District of Texas on January 4, 2002, Cause No. H02-0017, making general allegations of invalidity and non-infringement of US Patent No. 5,851,808 ("the '808 patent"), the parent of the captioned application. No art was submitted to substantiate the general allegations of invalidity; lack of best mode for the claims of the '808 patent was asserted. That Action has been dismissed by the Court; a copy of the Complaint for Declaratory Judgment is attached for the Examiner's convenience as Exhibit 1.

Applicant's representative also told the Examiner that opposing counsel in these cases has contended that certain deposition testimony is material to the claims of this current patent application. Applicant's representative summarized the deposition testimony as including testimony indicating that GST fusion proteins, cre recombinase and cre enzyme activity in the recombination of lox sites were all known prior to the priority date of the present application. As noted to the Examiner, these Allegations are contained in Clontech's motion to de-classify certain deposition testimony in the State Action that they contend is relevant to this patent application, attached hereto as Exhibit 2. Applicant's representative further noted to the Examiner that he did not consider this testimony to be material to the claims because it is cumulative to references that were considered by the Examiner. Applicant's representative also told the Examiner that no deponent suggested that the GST fusion of the present invention lacked novelty or is obvious.

Additionally, the Examiner was notified that opposing counsel has submitted a protest to the present application. Because this protest was not timely filed, it is possible that it has not been

placed in the file. Accordingly, it is attached to this paper for the Examiner's convenience as Exhibit 3.

In the final telephone interview with the Examiner on June 25, 2003, the Examiner requested Applicant's representative to provide a written statement or "letter" summarizing the communications to date so that the file could be returned to the Examiner for further consideration.

Accordingly, The present paper is being submitted to provide a record of these communications, and to submit to the Examiner for consideration the actual testimony and arguments of opposing counsel in the litigations discussed. Some brief remarks regarding this information are provided below.

#### ADDITIONAL REMARKS

Applicant's representative told the Examiner that the testimony is cumulative to references already of record and considered by the Examiner. At least some of those references are summarized below:

C40 Chong et al., *GENE* 192, 271-281, 1997 informed the Examiner that GST fusion proteins were known. The introduction of the paper begins: "Purification of recombinant proteins by the use of affinity tags is a convenient and widely used technology (Lavillie and McCoy 1995). A target protein is expressed as a fusion with an affinity tag which allows purification on an affinity column. A variety of affinity tags have been used, including *Schistosoma* glutathione S-transferase (GST) (Smith and Johnson, 1988), *Escherichia coli* maltose-binding protein (MBP) (Guan et al., 1988), *Staphylococcus* protein A (Nilsson and Abrahmsen, 1990), polyhistidine (Van Dyke et al., 1992), and calmodulin-binding peptide (Stofko-Hahn et al., 1992)." In addition, D39 Bai et al., *Cell* 86,263-274, 1996, describes a GST-SKP-1 fusion protein.

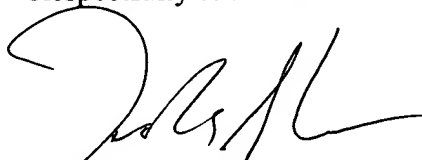
D45 Kolb and Siddell, *GENE* 183, 53-60, 1996 informed the Examiner that the Cre recombinase protein and its activity of recombination at *lox* sites was known. The first two

sentences of the abstract of this reference follow: "The Cre recombinase of bacteriophage P1 catalyses site-specific recombination between *lox*-recombination sites both in prokaryotic and eukaryotic cells and has thus become a popular tool in genetic research. Stable, Cre-mediated integration of DNA sequences at pre-existing *lox* sites in the eukaryotic genome is facilitated when a Cre recombinase protein rather than a *cre*-expression plasmid is used to direct site-specific recombination (Baubonis and Sauer (1993) Nucleic Acids Res., 21, 2025-2029)."

Applicants find no description of a GST-Cre fusion protein prior to the present invention and no suggestion of the desirability of such a GST-Cre fusion nor any suggestion that production of such a fusion would be successful. In fact, C245 Sheffield et al., *Protein Expression and Purification*, 15, 34-39, 1999 teaches away from the present invention by teaching that the tag fusion systems are beset with problems and are unpredictable. This reference, published after the priority date of the present claims, attempts to solve some of these problems of unpredictability by providing a family of parallel expression vectors that can be used in the production of fusion proteins.

Applicants submit, therefore, that the attached information is not material to the patentability of the allowed claims and request that those claims proceed to issue. If the Examiner does not agree with Applicant's position or with how the telephone communications have been summarized, or if he has any questions about this information upon review, a telephone call to the undersigned representative is respectfully urged.

Respectfully submitted

A handwritten signature in black ink, appearing to read 'T. S. Corder', with a large, sweeping initial 'T'.


Timothy S. Corder

38,414

Agent for Applicants



**CLONTECH'S MOTION TO SET ASIDE THE CONFIDENTIAL  
DESIGNATION OF CERTAIN DEPOSITION ADMISSIONS  
MATERIAL TO THE PATENTABILITY DETERMINATION  
OF BAYLOR'S PATENT APPLICATION CLAIMs**

nt. 

OF HARRIS COUNTY, TEXAS

133<sup>rd</sup> JUDICIAL DISTRICT

133<sup>rd</sup> JUDICIAL DISTRICT

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disclosing the Univector system. That patent application matured into U.S. Patent No. 5,851,808 ("the '808 patent") on December 22, 1998. Baylor filed at least one continuation-in-part patent application from the application that matured into the '808 patent, *i.e.*, U.S. Serial No. 09/122,384 ("the '384 application"). Baylor is believed to be the assignee of the '384 application.

Throughout discovery, Clontech repeatedly requested all documents concerning the '808 patent, which document requests encompassed any continuations and continuations-in-part thereof. On December 3, 2002, Clontech filed a motion to compel production of such documents. Clontech again explicitly requested all documents related to any continuation applications following the April 14, 2003 deposition of Charles Lipsey, during which Baylor's questioning implied that one or more continuation applications may be pending. (Ex. 1, Clontech's April 14, 2003 letter).

At the April 28, 2003 pretrial conference, the Court instructed the parties to inform the Special Master that all discovery motions should be decided promptly, by May 9, 2003. After the parties did so, counsel for Baylor agreed, for the first time, to provide the long requested discovery pertaining to the '808 patent. (Exs. 2 & 3, Ltrs. from Blanke to Oparil, May 2, 2003 and May 6, 2003).

On May 6, 2003, Baylor belatedly provided a letter to Clontech enclosing a Notice of Allowability in the '384 application, which was mailed by the PTO on April 22, 2003. (Ex. 4 hereto). Baylor also provided other documents to Clontech on May 15, 16, and 19, 2003 (received by Clontech on May 16, 17 and 20, 2003), which included information disclosed to the PTO.

The information Baylor provided to Clontech does not indicate that Baylor alerted the PTO to the existence of: (1) this litigation, (2) the Declaratory Judgment suit Clontech filed against Baylor – now dismissed – in the U.S. District Court for the Southern District of Texas, or (3) the deposition testimony that is material to the patentability of Baylor's claims.

### ARGUMENT

Individuals owe the PTO a duty of candor & good faith. See 37 C.F.R. § 1.56. ("Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability." "[I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a prima facie case of patentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes"). To comply with this duty under 37 C.F.R. § 1.56, applicants and applicants' representatives must disclose (1) the existence of litigation, and (2) any material information arising from that litigation related to the subject matter of the patent application, including deposition testimony. See, e.g., *Environ Products v. Total Containment, Inc.*, 43 U.S.P.Q. 2d 1288 (E.D. Pa. 1997); *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 68 F. Supp.2d 508 (D. N.J. 1999); see generally, Manual of Patent Examination Procedure ("MPEP") Section 2001.06(c).<sup>1</sup>

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<sup>1</sup> "Where the subject matter for which a patent is being sought is or has been involved in litigation, the existence of such litigation and any other material information arising therefrom must be brought to the attention of the Patent and Trademark Office. Examples of such material information include evidence of possible prior use or sales, questions of inventorship, prior art, allegations of 'fraud,' 'inequitable conduct,' and 'violation of duty of disclosure.' Another example of such material information is any assertion that is made during litigation which is contradictory to assertions made to the examiner. *Environ Prods., Inc. v. Total Containment, Inc.*, 43 U.S.P.Q. 2d 1288, 1291 (E.D. Pa. 1997). Such information might arise during litigation

The documents Baylor recently provided to Clontech include disclosures to the PTO, but do not include any disclosure of this ongoing litigation, the Federal Court Declaratory Judgment litigation or any disclosure of critical admissions that occurred in depositions taken during discovery in this case.

Clontech is bound by the protective order in this case, not to disclose information contained in the depositions designated as confidential pursuant to the protective order. (Ex. 5, Order dated October 28, 2002). Baylor has utilized this protective order to designate much of the information disclosed as "confidential" or "outside attorneys eyes only", and has designated the testimony of its witnesses as confidential, except that of Dr. Liu. Because Dr. Liu's testimony was not designated as being confidential, Clontech filed a Protest in the PTO with respect to the '384 application, disclosing relevant portions of Dr. Liu's transcript and the existence of this case (Ex. 6). As explained in the Protest, Dr. Liu admits, *inter alia*, that at the time of filing the application that led to the '808 patent (and, therefore, necessarily before filing the '384 invention therefrom), GST fusion proteins were known and the Cre enzyme was known:

Q: Okay. Now, GST fusion proteins were known in the art prior to your work, correct?

A: Correct.

Q: And the Cre enzyme itself was known in the art prior to your work, correct?

A: Correct.

Q: And am I correct in understanding that the Cre recombinases [sic recombinase], the Cre enzyme, its ability to recombine loxP site [sic sites] was also known in the art, correct?

A: Correct.

(Ex. 7, Liu Dep. at 15:23-16:8).

These admissions are material to the patentability of, for example, claims 43, 46, 48, 49, 52-54, 56 and 63 as they appear in the Preliminary Amendment that Baylor sent Clontech, which

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in, for example, pleadings, admissions, discovery including interrogatories, depositions, and other documents, and testimony." MPEP § 2001.06(c).

appear to have the same claim numbering as the allowed claims on the Notice of Allowability.  
(Ex. 4).

Additional admissions, which are believed to be material to the patentability of at least one of the claims, were made during the depositions of Drs. Elledge and Kreuzer and Ms. Li. Clontech cannot provide this information marked confidential to the PTO; however, Baylor can and should do so. In the event that Baylor does not comply with its duty of candor to the PTO, this Court should permit Clontech to provide the relevant portions of deposition transcripts to the PTO, notwithstanding the protective order. In particular, Baylor's witnesses admitted the following:

1. The Cre enzyme was known in the prior art to the filing of the application that matured into the '808 patent. (Li Dep. at 20:20-25, 22:21-23:10; Liu Dep. at 15:23-17:17; Elledge TRCP 199.2(b)(1) Dep. at 65:1-4; Elledge 2003 Dep. at 22:11-23:20; Kreuzer Dep. at 59:11-23).<sup>2</sup>
2. Elledge and Liu did not invent Cre. (Kreuzer Dep. at 59:11-23).
3. Each of the components of the Univector system was in the public domain prior to the filing of the application that matured into the '808 patent. (Liu Dep. at 15; Elledge 2003 Dep. at 22:11-23:20; Li Dep. at 20-24, 37, 39; Kreuzer Dep. at 55-56, 59).
4. Each of the components of the Univector system was in the public domain prior to any alleged invention of that system by Drs. Elledge and/or Liu. (Liu Dep. at 15; Elledge 2003 Dep. at 22:11-23:20; Li Dep. at 20-24, 37, 39; Kreuzer Dep. at 55-56, 59).
5. Cre-mediated recombination was in the public domain prior to the filing of the application that matured into the '808 patent. (Elledge TRCP 199.2(b)(1) Dep. at 65:1-4; Elledge 2003 Dep. at 22:11-23:20; Kreuzer Dep. at 75:2-78:23; Liu Dep. at 15:23-17:17).

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<sup>2</sup> Relevant excerpts from the Li deposition are attached as Ex. 8; relevant excerpts from the Elledge depositions are attached as Ex. 9; and relevant excerpts from the Kreuzer deposition are attached as Ex. 10.

6. Cre-mediated recombination using *lox P* sites was in the public domain prior to the filing of the '808 patent application. (Elledge TRCP 199.2(b)(1) Dep. at 65:1-4; Elledge 2003 Dep. at 22:11-23:20; Kreuzer Dep. at 75:2-78:23; Liu Dep. at 15:23-17:17; Li Dep. at 20:20-25, 21:5-8).
7. *Lox P*-recombination was in the public domain prior to the filing of the '808 patent application. (Elledge TRCP 199.2(b)(1) Dep. at 65:1-4; Liu Dep. at 15:23-17:17; Elledge 2003 Dep. at 22:11-23:20; Kreuzer Dep. at 80:12-82:33; Li at 20:20-25, 21:5-8).
8. GST-fusion proteins were in the public domain prior to the filing of the '808 patent application. (Kreuzer Dep. at 59:11-23; Li Dep. at 22:21-23:10; Liu Dep. at 15:23-17:17).
9. Conditional origins of replication were in the public domain prior to the filing of the '808 patent application. (Elledge TRCP 199.2(b)(1) Dep. at 66:20-22; Elledge 2003 Dep. at 22:11-23:20; Kreuzer at 55:11-56:5).
10. The use of a conditional origin of replication as a selection means was in the public domain prior to the filing of the '808 patent application. (Elledge 2003 Dep. at 22:11-23:20; Kreuzer at 55:11-56:5; Li Dep. at 39:2-15).
11. Subcloning was in the public domain prior to the filing of the '808 patent application. (Elledge 2003 Dep. at 24:8-25:18).
12. Subcloning using plasmids was in the public domain prior to the filing of the '808 patent application. (Elledge 2003 Dep. at 24:8-25:18).
13. Subcloning using restriction modification of plasmids was in the public domain prior to the filing of the '808 patent application. (Elledge 2003 Dep. at 24:8-25:18).

Clontech requests this Court permit it to provide the above-referenced material to the PTO and thereby permit to PTO to properly examine the patent application at issue.

The prosecution documents Baylor recently provided to Clontech indicate that Baylor's claim scope has varied tremendously during the prosecution of the '384 application. In fact, vastly different claims were pursued in this application and were allowed twice, twice being withdrawn from issuance before canceling all of the claims and adding the new claims in the October 3, 2002 Preliminary Amendment. The prosecution history also shows a restriction

requirement, which could very well indicate that one or more divisional applications have been or will be filed pursuing claims of a different scope than those claims presently allowed. Accordingly, the protective order should be set aside for the sole purpose of providing material to the PTO not just with respect to the information material to what may be the presently allowed claims (the scope of which Clontech has no way of confirming), but also with respect to all other admissions that are material to claims Baylor may attempt to add to this or a divisional or continuing application, based on the disclosure of the '384 application.

Thus, this Court should set aside the protective order with respect to all of the above information, and any additional information, which is material to the patentability of any potential claims Baylor presently or may pursue, which Baylor is required to submit to the PTO pursuant to its obligations under 37 C.F.R. § 1.56.

#### CONCLUSION

For all the foregoing reasons, Clontech's motion should be granted.

Dated: May 23, 2003

BRACEWELL & PATTERSON LLP

By: 

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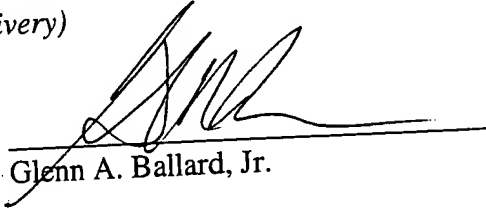
**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that they caused the foregoing to be served on May 23, 2003, on the following:

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April 14, 2003

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**VIA FACSIMILE**

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Re: *Baylor College of Medicine, et al. v. Clontech Laboratories, Inc. v. Invitrogen Corp.*  
Cause No. 2001-61352

Dear David:

Further to my request at the conclusion of the April 14, 2003 deposition of Charles Lipsey, please provide us with the following documents immediately:

- (1) the exhibits marked at Ruo Bo Zhang's deposition, and
- (2) all documents relating to all continuations from or other U.S. patent applications related to the '808 patent

With regard to the latter request, we are aware that at least one such continuation application exists. In particular, as shown on the enclosed Patent Application Information Retrieval search of continuity data, U.S. Patent Application 09/122,384 is a pending continuation application from the application that matured into the '808 patent. Clontech long ago requested information pertaining to Baylor's '808 patent. Baylor chose to object to providing such information and required Clontech to file a (pending) Motion to Compel. As demonstrated in the questions you posed to Mr. Lipsey, these documents are relevant to the claims and defenses in this action.

Please let us know when we may expect to receive the requested documents.

Very truly,

A handwritten signature in black ink, appearing to read 'R. Oparil'.

Richard J. Oparil

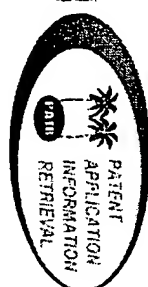
Enclosures

cc: Glenn A. Ballard, Jr., Esq.



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Search results for patent number: 5,851,808			
Application Number:	08/864,224	Class / Sub-Class:	435/172.300
Filing or 371(c) Date:	02-28-1997	Location:	-
Issue Date of Patent:	12-22-1998	Status:	-
Examiner Name:	RAILEY, JOHNNY	Group Art Unit:	1636
Earliest Publication No.:	-	Attorney Docket	BCM-02681
Earliest Publication	-	Customer Number:	-
Confirmation Number:	6512		

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Child Continuity Data	
09/122,384 filed on 07-24-1998 which is Pending claims the benefit of 08/864,224	

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Filing or 371(c) Date:	02-28-1997	Class / Sub-Class:	435/172.300
Issue Date of Patent:	12-22-1998	Location:	-
Examiner Name:	RAILEY, JOHNNY	Status:	-
Group Art Unit:	1636	Attorney Docket	BCM-02681
Earliest Publication No.:	-	Patent Number:	5,851,808
Earliest Publication	-	Customer Number:	-
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May 2, 2003

*By Fax*

Mr. Richard J. Oparil  
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Re: *Baylor College of Medicine, et al. v. Clontech Laboratories, Inc.;*  
Cause No. 2001-61352

Dear Richard:

I am writing to confirm what I believe is our agreement to considerably narrow the issues raised in Clontech's Motion to Compel Discovery from Baylor. Below I will refer to the headings in the motion and recount what I understand to be the agreement.

***"Baylor Should be Compelled to Produce Documents Regarding the Reorganization of BCMT and BCM's Office of Technology Administration."*** We have reconfirmed that there are no such documents.

***"Baylor Should be Compelled to Confirm that the Files of Certain Baylor Employees and/or Former Employees Have Been Searched and Responsive Documents Produced."*** ***"Baylor Should be Compelled to Confirm that Certain Relevant Locations at Baylor Have Been Searched and All Responsive Documents Produced."*** We have confirmed that the records of the persons listed in the motion have been searched, as have the locations specified in the motion.

***"Baylor Should be Compelled to Produce Its Documents Pertaining [to] the Harvard FLEXGene Consortium."*** We agreed to determine whether Baylor has a copy of Invitrogen's proposal or any documents relating to such proposal. We have confirmed that Invitrogen never provided its Harvard FLEXgene Consortium application or response to request for proposal to Baylor nor did Baylor correspond with Invitrogen or have any other communication with Invitrogen about the Consortium.

Mr. Richard J. Oparil  
Page 2  
May 2, 2003

***"Baylor Should be Compelled to Produce All Slides, Notes and Similar Material Presented at Conferences or Other Public Events Pertaining to the Elledge Technology."*** We have reconfirmed that there are no such materials. In doing so, we obtained and reviewed the Medlen & Carroll firm's records.

***"Baylor Should be Compelled to Produce All 1998 Calendars of Drs. Elledge, Li, and/or Liu Relating to the Elledge Technology."*** We are determining whether such calendars exist for Drs. Elledge and Li. If so, we will produce the entries that pertain to any presentation of the Univector System or circulation of it to researchers. As I explained on the telephone, we do not have possession, custody, or control of Dr. Liu's calendar.

***"Baylor Should be Compelled to Produce All Documents Relating to the '808 Patent."*** We are reexamining these requests. We will produce all non-privileged responsive documents relating to the '808 patent and any related applications.

***"Baylor Should be Compelled to Produce All of Its Responsive Lab Notebooks and Other Documents Sought in Request for Production No. 2."*** We have confirmed that all responsive notebooks have been produced. The complete record of the development of the Univector System is set forth in Dr. Liu's lab notebook and in other records of the Elledge laboratory, which were produced early in the litigation. The bates range of the Liu notebook is BCM 658-939. A comprehensive search of the Elledge laboratory's records were made and all other relevant pages from the laboratory notebooks of Dr. Elledge, Dr. Liu and Mamie Li were provided at bates ranges BCM 393-657 and 940-1027.

***"Baylor Should be Compelled to Fully Respond to Requests for Production Nos. 15 and 16."*** We are reconfirming that nothing further exists and will then write to confirm as much or produce what non-privileged documents that may be located.

***"Baylor Should be Compelled to Produce Documents Responsive to Request for Production No. 17."*** Clontech withdraws this request from the motion.

***"Baylor Should be Compelled to State the Dates of Disclosure of Information that Baylor Alleges are Trade Secrets."*** The interrogatory response will be amended to include dates or approximate time frames (if no specific date can be determined), based on the marketing log and other records, some of which are in Clontech's files.

***"Baylor Should be Compelled to Supplement its Incomplete Responses to Interrogatories Nos. 4, 11 and Any Other Interrogatories for Which Baylor Withheld Information Relating to the '808 Patent."*** We will amend the response to the interrogatory to refer Clontech to the marketing log. Interrogatory No. 11 will be amended to specify that Drs. Elledge and Liu are the inventors (as the '808 patent reflects).

Mr. Richard J. Oparil  
Page 3  
May 2, 2003

***"Baylor Should be Compelled to Supplement its Incomplete Response to Interrogatory No. 7, and All Other Interrogatories That Were Not Fully Responded to Because No Protective Order Was in Place."*** Clontech has deposed each of the Baylor and Invitrogen participants in those negotiations. Baylor has produced its marketing log, which details those discussions. And Invitrogen produced other materials that you used at the recent Invitrogen depositions. I have confirmed that no information was withheld on the basis that there was, at the time of the interrogatory, no protective order. With this confirmation, I understand Clontech withdraws its request for a supplemental response to interrogatory nos. 4, 5, and 7.

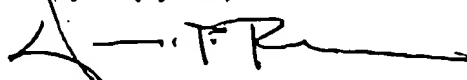
***"Baylor Should be Compelled to Fully Respond to Interrogatory Nos. 8 and 9."*** Baylor will amend its response to refer Clontech to the royalty reports (most of which are exhibits to the initial Baylor depositions).

***"Baylor Should be Compelled to Either Produce the Documents Requested in Clontech's July 30, 2002 Letter or Confirm that all Responsive Documents Have Been Produced."*** We are reconfirming that there are no additional non-privileged responsive documents. We will then write to confirm as much or produce what non-privileged documents that may be located.

***"Baylor Should be Compelled to Produce Responsive Internal Communications."*** We have reconfirmed that there are no additional responsive, non-privileged documents.

If the foregoing is correct, please countersign this letter and return it to our offices. We will tend to filing the letter with the Court, *see* TEX. R. CIV. P. 11, and circulating a copy to Jack Goldstein.

Very truly yours,



David P. Blanke

**AGREED:**

---

Richard J. Oparil

*Attorney for Clontech Laboratories, Inc.*



Mr. Richard J. Oparil

Page 4

May 2, 2003

c: Glenn A. Ballard, Jr. (*by fax*)  
Tracey B. Davies [*Firm*]  
M. Michelle Muller [*Firm*]  
Jason M. Powers [*Firm*]



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3 MAY -2 P6:29

David P. Blanke  
Direct Dial (512) 542-8622  
Direct Fax (512) 236-3314  
dblanke@velaw.com

## FACSIMILE TRANSMITTAL PAGE

DATE: May 2, 2003

TO: Glenn A. Ballard, Jr.  
Bracewell & Patterson

FAX: 713.221.1212

PHONE: 713.223.2900

TO: Richard J. Oparil  
Patton Boggs (DC)

FAX: 202.457.6315

PHONE: 202.457.6000

PAGES: 5 (including this transmittal page)

CLIENT/MATTER: INV850/13000

FROM: David P. Blanke

MESSAGE: David Blanke's 05/02/03 letter to Oparil re agreements to narrow issues in Clontech's motion to compel discovery from Baylor.

Hard Copy Follows: ☐ Yes ☒ No

### CONFIDENTIALITY NOTICE:

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Direct Fax (512) 236-3314  
dblankc@vclaw.com

May 6, 2003

*By Fax*

Mr. Richard J. Oparil  
Patton Boggs L.L.P.  
2550 M Street NW  
Washington, DC 20037

Re: *Baylor College of Medicine, et al. v. Clontech Laboratories, Inc.;*  
Cause No. 2001-61352

Dear Richard:

I am further responding to your April 14 letter. Earlier I wrote regarding the Ruobo Zhang exhibits. As to the '808 continuations, we will be producing the non-privileged documents on this issue. In the meantime, I am providing the accompanying preliminary amendment and notice of allowance from the PTO.

Very truly yours,

David P. Blanke

attachment

c: Glenn A. Ballard, Jr. (*by fax; w/att.*)  
Kevin Bell (*by fax; w/att.*)  
Tracey B. Davies [*Firm; w/o att.*]  
M. Michelle Muller [*Firm; w/o att.*]  
Jason M. Powers [*Firm; w/o att.*]

**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: ASSISTANT COMMISSIONER FOR PATENTS

Washington, D.C. 20231

APPLICATION NO/ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR/ PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
--------------------------------	-------------	--	---------------------

EXAMINER
----------

ART UNIT	PAPER
----------	-------

47

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

--See attached--

**Notice of Allowability**

Application No.

09/122,384

Applicant(s)

ELLEDGE ET AL.

Examiner

Art Unit

James S. Ketter

1636

**- The MAILING DATE of this communication appears on the cover sheet with the correspondence address-**  
 All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- ☒ This communication is responsive to the amendment of 10/3/02 and the IDS of 3/4/03.
- ☒ The allowed claim(s) is/are 43-68.
- ☒ The drawings filed on 20 March 2001 are accepted by the Examiner.
- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some c) ☐ None of the:
    - 1. ☐ Certified copies of the priority documents have been received.
    - 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    - 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.
- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a) ☐ The translation of the foreign language provisional application has been received.
- ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted above. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

☐ CORRECTED DRAWINGS must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.

(b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.

(c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statements (PTO-1449), Paper No. 70, 72 & 45.
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

- 2 ☐ Notice of Informal Patent Application (PTO-152)
- 4 ☐ Interview Summary (PTO-413), Paper No. \_\_\_\_\_
- 6 ☐ Examiner's Amendment/Comment
- 8 ☐ Examiner's Statement of Reasons for Allowance
- 9 ☐ Other

**JAMES KETTER  
PRIMARY EXAMINER**

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
ADDRESSEE: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
Phone: (202) 291-4000

## DATE MAILED- 04/22/2003

PTOL-85 (REV. 04-02) Approved for use through 01/31/2004.

## PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Box ISSUE FEE  
 Commissioner for Patents  
 Washington, D.C. 20231  
 Fax (703)746-4000

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Please Legibly Print - up with any correction of the above)

21586

7590

04/22/2003

VINSON & ELKINS, L.L.P.  
 1001 FANNIN STREET  
 2300 FIRST CITY TOWER  
 HOUSTON, TX 77002-6760

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission  
 I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above, or being facsimile transmitted to the USPTO, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/123,384	07/24/1998	STEPHEN J. ELLEDGE	BAY1364-010CIP	4340

TITLE OF INVENTION: RAPID SUBCLONING USING SITE-SPECIFIC RECOMBINATION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1300	\$0	\$1300	07/22/2003

EXAMINER	ART UNIT	CLASS-SUBCLASS
KETTER, JAMES S	1636	435-008000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1. \_\_\_\_\_  
 2. \_\_\_\_\_  
 3. \_\_\_\_\_

## 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) ☐ individual ☐ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:

☐ Issue Fee

☐ Publication Fee

☐ Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s):

☐ A check in the amount of the fee(s) is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Commissioner is hereby authorized to charge the required fee(s), or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature)

(Date)

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant, a registered attorney or agent, or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMIT THIS FORM WITH FEE(S)

PTOL-85 (REV. 04-02) Approved for use through 01/31/2004. OMB 0651-0033

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/122,384	07/24/1998	STEPHEN J. ELLEDGE	BAY136/4-010CIP	4340
21386	7590	04/22/2003	EXAMINER	
VINSON & ELKINS, L.L.P. 1001 FANNIN STREET 2300 FIRST CITY TOWER HOUSTON, TX 77002-6760			KETTER, JAMES S	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 04/22/2003

**Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**  
(application filed on or after May 29, 2000)

The patent term adjustment to date is 0 days. If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the term adjustment will be 0 days.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (<http://pair.uspto.gov>)

Any questions regarding the patent term extension or adjustment determination should be directed to the Office of Patent Legal Administration at (703)305-1383.





## UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/122,384	07/24/1998	STEPHEN J. ELLEDGE	BAY1364-010CIP	4340
21586	7590	04/22/2003	EXAMINER	
VINSON & ELKINS, L.L.P. 1001 FANNIN STREET 2300 FIRST CITY TOWER HOUSTON, TX 77002-6760 UNITED STATES			KETTER, JAMES S	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 04/22/2003

## Notice of Fee Increase on January 1, 2003

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after January 1, 2003, then the amount due will be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there will be an increase in fees effective on January 1, 2003. See Revision of Patent and Trademark Fees for Fiscal Year 2003, Final Rule, 67 Fed. Reg. 70847, 70849 (November 27, 2002).

The current fee schedule is accessible from: <http://www.uspto.gov/main/howtofees.htm>.

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of the fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filed on or after January 1, 2003 (or mailed with a certificate of mailing on or after January 1, 2003), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

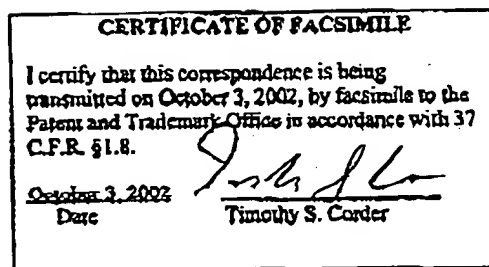
Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

**Vinson & Elkins**  
ATTORNEYS AT LAW

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Timothy S. Corder  
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tcorder@velaw.com

October 3, 2002



Assistant Commissioner for Patents  
Washington, D.C. 20231

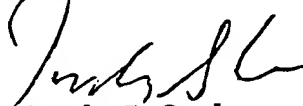
Re: U.S. Patent Application SN 09/122,384 "Rapid Subcloning Using Site-Specific Recombination," by Elledge et al.  
Attorney Docket No.: BAY136/4-010CIP/36000; Client Ref.: OTA # 97-27  
Confirmation No. 4340

Sir,

Enclosed for filing in the above-referenced patent application is a Preliminary Amendment for filing in the above-referenced patent application.

It is believed that no fee is due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Assistant Commissioner is authorized to appropriately deduct or credit the requisite amount from Vinson & Elkins L.L.P. deposit account No. 22-0365/BAY136/4-010CIP/36000.

Respectfully submitted,

  
Timothy S. Corder  
Reg. No. 38,414

9282:5588

Enclosure

311728\_1.DOC

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**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Stephen J. Elledge et al.

Serial No.: 09/122,384

Filed: July 24, 1998

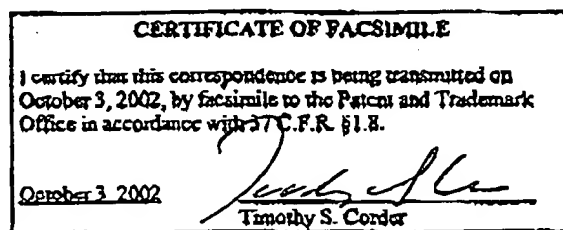
For: Rapid Subcloning Using Site-Specific  
Recombination

Group Art Unit: 1636

Examiner: J. Ketter

Atty. Dkt. No.: BAY136/4-10CIP/36000

Confirmation No. 4340



**PRELIMINARY AMENDMENT**

**VIA FACSIMILE NO. 703-746-5155**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In advance of prosecution, the Examiner is requested to please amend the above-captioned application as follows:

**AMENDMENT**

**A. In the Claims:**

Please cancel all pending claims, i.e. claims 1-20, 26, 30-35, and 37-42, and enter the following new claims:

43. A composition comprising a glutathione-S-transferase-Cre-recombinase fusion polypeptide.

44. The composition of claim 43, wherein the polypeptide has an amino acid sequence according to SEQ ID NO:11.
45. The composition of claim 43, wherein the composition comprises an enzyme activity with a Cre recombinase efficiency of about 16.8% per microgram of protein.
46. An isolated nucleic acid molecule comprising a coding region wherein the coding region encodes a glutathione-S-transferase-Cre-recombinase fusion polypeptide.
47. The nucleic acid molecule of claim 46, wherein the coding region comprises the nucleic acid sequence of SEQ ID NO:10.
48. The nucleic acid molecule of claim 46, wherein the isolated nucleic acid molecule is an expression vector.
49. The nucleic acid molecule of claim 46, wherein the coding region is operatively linked to a promoter effective to direct expression of a glutathione-S-transferase-Cre recombinase fusion polypeptide.
50. The nucleic acid molecule of claim 49, wherein the promoter is an inducible promoter.
51. The nucleic acid of claim 50, wherein the promoter is the *tac* promoter.
52. A host cell comprising the nucleic acid molecule of claim 46.
53. A host cell comprising the nucleic acid molecule of claim 49.
54. The host cell of claim 53, wherein the host cell expresses a Cre recombinase activity.

55. The host cell of claim 53, further defined as an E. coli cell.
56. A bacterial cell engineered to express a glutathione-S-transferase-Cre-recombinase fusion polypeptide.
57. The bacterial cell of claim 56, wherein the polypeptide has an amino acid sequence according to SEQ ID NO:11.
58. A method of producing a glutathione-S-transferase-Cre-recombinase fusion polypeptide comprising:  
obtaining an expression vector comprising a coding region encoding a glutathione-S-transferase-Cre-recombinase fusion polypeptide operatively linked to a promoter;  
transforming or transfecting the vector into a cell; and  
growing the cell under conditions effective to express a glutathione-S-transferase-Cre-recombinase fusion polypeptide.
59. The method of claim 58, further comprising isolating the glutathione-S-transferase-Cre-recombinase fusion polypeptide.
60. The method of claim 59, wherein isolating the polypeptide comprises glutathione affinity chromatography.
61. A method of recombining nucleic acid segments, wherein each segment comprises a *lox* site specific recombinase site, the method comprising contacting the nucleic acid segments with a glutathione-S-transferase-Cre-recombinase fusion polypeptide.
62. The method of claim 61, wherein the polypeptide has an amino acid sequence according to SEQ ID NO:11.

63. A composition comprising a glutathione-S-transferase-Cre-recombinase fusion polypeptide and one or more nucleic acid molecules, wherein the nucleic acids comprise a site specific recombinase site.
64. The composition of claim 63, wherein at least one of said nucleic acid molecules comprises a lox recombination site upstream in a 5' to 3' orientation from an amino acid encoding region.
65. The composition of claim 63, wherein at least one of said nucleic acid molecules comprises a transcription regulatory element upstream in a 5' to 3' orientation of a lox recombinase site.
66. The composition of claim 64 wherein the lox recombinase site is a *loxP*, *loxP2*, *loxP3*, *loxP23*, *loxP511*, *loxB*, *loxC2*, *loxL*, *loxR*, *lox486*, *lox4117*, or *loxH* site.
67. The composition of claim 65 wherein the lox recombinase site is a *loxP*, *loxP2*, *loxP3*, *loxP23*, *loxP511*, *loxB*, *loxC2*, *loxL*, *loxR*, *lox486*, *lox4117*, or *loxH* site.
68. The composition of claim 64, wherein the amino acid encoding region is a member of a nucleic acid library.

## II. REMARKS

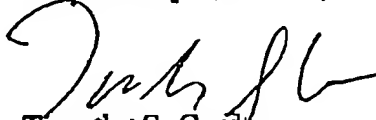
The claims in this preliminary amendment do not add new matter to the application and their entry is therefore respectfully requested. Support for the claims may be found throughout the Specification and at least in Example 3 found on page 47.

## IV. CONCLUSION

Applicants respectfully submit that the present application and all claims are in condition for immediate allowance and early notice to such effect is earnestly solicited. If, in the opinion of the Examiner, a phone call may help expedite prosecution of this application, the Examiner is invited to contact the undersigned representative at (512) 542-8446.

It is believed that no fee is due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Assistant Commissioner is authorized to deduct said fees from Vinson & Elkins L.L.P. Deposit Account No. 22-0365/BAY136/4-10CIP/36000.

Respectfully submitted,



Timothy S. Corder  
Reg. No. 38,414  
Agent for Applicant

Vinson & Elkins L.L.P.  
2300 First City Tower  
1001 Fannin  
Houston, Texas 77002-6760  
512/542-8446

Date: October 3, 2002



VINSON & ELKINS L.L.P.  
THE TERRACE 7  
2801 VIA FORTUNA, SUITE 100  
AUSTIN, TEXAS 78746  
TELEPHONE (512) 542-8400  
FAX (512) 542-8612  
www.vclaw.com

5 MAY -6 P1:59

David P. Blanke  
Direct Dial (512) 542-8622  
Direct Fax (512) 236-3314  
dblank@vclaw.com

## FACSIMILE TRANSMITTAL PAGE

DATE: May 6, 2003

Glenn A. Ballard, Jr.  
Bracewell & Patterson

FAX: 713.221.1212

PHONE: 713.223.2900

TO: Marc Labgold  
Kevin M. Bell  
Patton Boggs (VA)

FAX: 703.744.8001

PHONE: 703.744.8000

TO: Richard J. Oparil  
Patton Boggs (DC)

FAX: 202.457.6315

PHONE: 202.457.6000

PAGES: 14 (including this transmittal page)

CLIENT/MATTER: INV850/13000

FROM: David P. Blanke

MESSAGE: David Blanke's 05/06/03 letter further responding to 04/14/03 Oparil letter.

Hard Copy Follows ☐ Yes ☒ No

### CONFIDENTIALITY NOTICE:

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---

To:	Amy Bell
Company:	Patton Boggs LLP
Fax Number:	703.744.8001
Phone Number:	703.744.8000

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Total Pages Including Cover:	15
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From:	Richard Oparil
Sender's Direct Line:	202.457.6496
Date:	May 6, 2003
Client Number:	020187.0102

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Comments:

ANCHORAGE

BOULDER

DALLAS

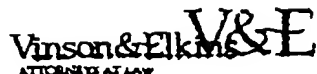
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5 MAY -6 P1:59

David P. Blanke  
Direct Dial (512) 542-8622  
Direct Fax (512) 236-3314  
dblank@velaw.com

## FACSIMILE TRANSMITTAL PAGE

DATE: May 6, 2003

Glenn A. Ballard, Jr.  
Bracewell & Patterson

FAX: 713.221.1212

PHONE: 713.223.2900

TO: Marc Labgold  
Kevin M. Bell  
Patton Boggs (VA)

FAX: 703.744.8001

PHONE: 703.744.8000

TO: Richard J. Oparil  
Patton Boggs (DC)

FAX: 202.457.6315

PHONE: 202.457.6000

PAGES: 14 (including this transmittal page)

CLIENT/MATTER: INV850/13000

FROM: David P. Blanke

MESSAGE: David Blanke's 05/06/03 letter further responding to 04/14/03 Oparil letter.

Hard Copy Follows ☐ Yes ☒ No

### CONFIDENTIALITY NOTICE:

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May 6, 2003

**By Fax**

Mr. Richard J. Oparil  
Patton Boggs L.L.P.  
2550 M Street NW  
Washington, DC 20037

Re: *Baylor College of Medicine, et al. v. Clontech Laboratories, Inc.;*  
Cause No. 2001-61352

Dear Richard:

I am further responding to your April 14 letter. Earlier I wrote regarding the Ruobo Zhang exhibits. As to the '808 continuations, we will be producing the non-privileged documents on this issue. In the meantime, I am providing the accompanying preliminary amendment and notice of allowance from the PTO.

Very truly yours,

David P. Blanke

attachment

c: Glenn A. Ballard, Jr. (by fax; w/att.)  
Kevin Bell (by fax; w/att.)  
Tracey B. Davies [Firm; w/o att.]  
M. Michelle Muller [Firm; w/o att.]  
Jason M. Powers [Firm; w/o att.]



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: ASSISTANT COMMISSIONER FOR PATENTS

Washington, D.C. 20231

APPLICATION NO/ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
--------------------------------	-------------	---	---------------------

EXAMINER
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ART UNIT	PAPER
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47

DATE MAILED:

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

--See attached--

**Notice of Allowability**

Application No.

09/122,384

Applicant(s)

ELLEDEGE ET AL

Examiner

James S. Ketter

Art Unit

1836

**- The MAILING DATE of this communication appears on the cover sheet with the correspondence address-**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment of 10/3/02 and the IDS of 3/4/03.
2. ☒ The allowed claim(s) is/are 43-68.
3. ☒ The drawings filed on 20 March 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
  - (a) ☐ including changes required by the Notice of Draftperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)  
☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  
☒ Information Disclosure Statements (PTO-1449), Paper No. 70, 72 & 73.  
☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

- ☐ Notice of Informal Patent Application (PTO-152)  
☐ Interview Summary (PTO-413), Paper No. \_\_\_\_\_  
☐ Examiner's Amendment/Comment  
☐ Examiner's Statement of Reasons for Allowance  
☐ Other

**JAMES KETTER**  
**PRIMARY EXAMINER**

1741126/11471126

172



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20530  
www.uspto.gov

## NOTICE OF ALLOWANCE AND FEE(S) DUE

21586 7390 04/22/2003

VINSON & ELKINS, L.L.P.  
1001 FANNIN STREET  
2300 FIRST CITY TOWER  
HOUSTON, TX 77002-6760

RECEIVED

APR 28 2003

IF Docket Office  
Vinson & Elkins

EXAMINER

KBTTER, JAMES S

ART UNIT

CLASS-SUBCLASS

1636

415-006000

DATE MAILED: 04/22/2003

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/122,384	07/24/1998	STEPHEN J. ELLEDGE	BAY 1364-010CIP	4340

TITLE OF INVENTION: RAPID SUBCLONING USING SITE-SPECIFIC RECOMBINATION

APPL. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1300	\$0	\$1300	07/22/2003

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

## HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status.  
See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

## PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Box ISSUE FEE  
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Washington, D.C. 20231  
Fax (703)746-4000

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, Advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notification.

CURRENT CORRESPONDENCE ADDRESS (Name) Legally mail-up with any change in the name of the inventor

31586 7590 04/22/2003

VINSON & ELKINS, L.L.P.  
1001 FANNIN STREET  
2300 FIRST CITY TOWER  
HOUSTON, TX 77002-6760

Note: A certificate of mailing can only be used for domestic filings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

## Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above, or being facsimile transmitted to the USPTO, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/12/1994	07/24/1998	STEPHEN J. ELLEDGE	BAY1364-010C1P	6340

TITLE OF INVENTION: RAPID SUBCLONING USING SITE-SPECIFIC RECOMBINATION.

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1300	\$0	\$1300	07/22/2003

EXAMINER	ART UNIT	CLASS-SUBCLASS
KETTER JAMES S	1636	435-006000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1	_____
2	_____
3	_____

## 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY AND STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) ☐ individual ☐ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:

- ☐ Issue Fee
- ☐ Publication Fee
- ☐ Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s):

- ☐ A check in the amount of the fee(s) is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature)

(Date)

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant, a registered attorney or agent, or the assignee or other party to interest as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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TRANSMIT THIS FORM WITH FEE(S)

PTOL-85 (REV. 04-02) Approved for use through 01/31/2004. OMB 0651-0003

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/122,384	07/24/1996	STEPHEN J. ELLEDGE	BAY1364-010CIP	4340
21586	7590	04/22/2003	EXAMINER	
VINSON & ELKINS, L.L.P. 1001 FANNIN STREET 2300 FIRST CITY TOWER HOUSTON, TX 77002-6760			KETTER, JAMES S	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 04/22/2003				

**Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**  
 (application filed on or after May 29, 2000)

The patent term adjustment to date is 0 days. If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the term adjustment will be 0 days.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (<http://pair.uspto.gov>)

Any questions regarding the patent term extension or adjustment determination should be directed to the Office of Patent Legal Administration at (703)305-1383.





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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/122,384	07/24/1998	STEPHEN J. ELLEDGE	RAY1364-010CIP	4340
21584	7590	04/22/2003	EXAMINER	
VINSON & ELKINS, L.L.P. 1001 FANNIN STREET 2300 FIRST CITY TOWER HOUSTON, TX 77002-6760 UNITED STATES			KETTER, JAMES S	
			ART IDNT	PAPER NUMBER
			1636	
DATE MAILED: 04/22/2003				

## Notice of Fee Increase on January 1, 2003

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after January 1, 2003, then the amount due will be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there will be an increase in fees effective on January 1, 2003. See Revision of Patent and Trademark Fees for Fiscal Year 2003: Final Rule, 67 Fed. Reg. 70847, 70849 (November 27, 2002).

The current fee schedule is accessible from: <http://www.uspto.gov/main/howtofees.htm>.

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of the fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filed on or after January 1, 2003 (or mailed with a certificate of mailing on or after January 1, 2003), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

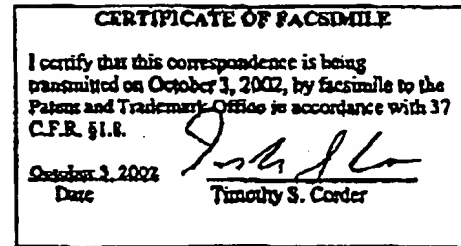
Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

**Vinson & Elkins**  
ATTORNEYS AT LAW

VINSON & ELKINS L.L.P.  
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tcorder@velaw.com

October 3, 2002



Assistant Commissioner for Patents  
Washington, D.C. 20231

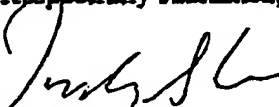
Re: U.S. Patent Application SN 09/122,384 "Rapid Subcloning Using Site-Specific Recombination," by Elledge et al.  
Attorney Docket No.: BAY136/4-010CIP/36000; Client Ref.: OTA # 97-27  
Confirmation No. 4340

Sir:

Enclosed for filing in the above-referenced patent application is a Preliminary Amendment for filing in the above-referenced patent application.

It is believed that no fee is due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Assistant Commissioner is authorized to appropriately deduct or credit the requisite amount from Vinson & Elkins L.L.P. deposit account No. 22-0365/BAY136/4-010CIP/36000.

Respectfully submitted,

  
Timothy S. Corder  
Reg. No. 38,414

9282:5588

Enclosure

311728\_1.DOC

AUSTIN • BEIJING • DALLAS • HOUSTON • LONDON • MOSCOW • NEW YORK • SINGAPORE • WASHINGTON, D.C.

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Stephen J. Elledge et al.

Serial No.: 09/122,384

Filed: July 24, 1998

For: Rapid Subcloning Using Site-Specific  
Recombination

Group Art Unit: 1636

Examiner: J. Ketter

Att. Dkt. No.: BAY136/4-10CIP/36000

Confirmation No. 4340

**CERTIFICATE OF FACSIMILE**

I certify that this correspondence is being transmitted on  
October 3, 2002, by facsimile to the Patent and Trademark  
Office in accordance with 37 C.F.R. §1.8.

October 3, 2002

  
Timothy S. Conder

**PRELIMINARY AMENDMENT**

**VIA FACSIMILE NO. 703-746-5155**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In advance of prosecution, the Examiner is requested to please amend the above-captioned application as follows:

**AMENDMENT**

**A. In the Claims:**

Please cancel all pending claims, i.e. claims 1-20, 26, 30-35, and 37-42, and enter the following new claims:

43. A composition comprising a glutathione-S-transferase-Cre-recombinase fusion polypeptide.

44. The composition of claim 43, wherein the polypeptide has an amino acid sequence according to SEQ ID NO:11.
45. The composition of claim 43, wherein the composition comprises an enzyme activity with a Cre recombinase efficiency of about 16.8% per microgram of protein.
46. An isolated nucleic acid molecule comprising a coding region wherein the coding region encodes a glutathione-S-transferase-Cre-recombinase fusion polypeptide.
47. The nucleic acid molecule of claim 46, wherein the coding region comprises the nucleic acid sequence of SEQ ID NO:10.
48. The nucleic acid molecule of claim 46, wherein the isolated nucleic acid molecule is an expression vector.
49. The nucleic acid molecule of claim 46, wherein the coding region is operatively linked to a promoter effective to direct expression of a glutathione-S-transferase-Cre recombinase fusion polypeptide.
50. The nucleic acid molecule of claim 49, wherein the promoter is an inducible promoter.
51. The nucleic acid of claim 50, wherein the promoter is the *tac* promoter.
52. A host cell comprising the nucleic acid molecule of claim 46.
53. A host cell comprising the nucleic acid molecule of claim 49.
54. The host cell of claim 53, wherein the host cell expresses a Cre recombinase activity.

55. The host cell of claim 53, further defined as an *E. coli* cell.
56. A bacterial cell engineered to express a glutathione-S-transferase-Cre-recombinase fusion polypeptide.
57. The bacterial cell of claim 56, wherein the polypeptide has an amino acid sequence according to SEQ ID NO:11.
58. A method of producing a glutathione-S-transferase-Cre-recombinase fusion polypeptide comprising:  
obtaining an expression vector comprising a coding region encoding a glutathione-S-transferase-Cre-recombinase fusion polypeptide operatively linked to a promoter;  
transforming or transfecting the vector into a cell; and  
growing the cell under conditions effective to express a glutathione-S-transferase-Cre-recombinase fusion polypeptide.
59. The method of claim 58, further comprising isolating the glutathione-S-transferase-Cre-recombinase fusion polypeptide.
60. The method of claim 59, wherein isolating the polypeptide comprises glutathione affinity chromatography.
61. A method of recombining nucleic acid segments, wherein each segment comprises a *lox* site specific recombinase site, the method comprising contacting the nucleic acid segments with a glutathione-S-transferase-Cre-recombinase fusion polypeptide.
62. The method of claim 61, wherein the polypeptide has an amino acid sequence according to SEQ ID NO:11.

63. A composition comprising a glutathione-S-transferase-Cre-recombinase fusion polypeptide and one or more nucleic acid molecules, wherein the nucleic acids comprise a site specific recombinase site.
64. The composition of claim 63, wherein at least one of said nucleic acid molecules comprises a lox recombination site upstream in a 5' to 3' orientation from an amino acid encoding region.
65. The composition of claim 63, wherein at least one of said nucleic acid molecules comprises a transcription regulatory element upstream in a 5' to 3' orientation of a lox recombinase site.
66. The composition of claim 64 wherein the lox recombinase site is a *loxP*, *loxP2*, *loxP3*, *loxP23*, *loxP511*, *loxB*, *loxC2*, *loxL*, *loxR*, *lox486*, *lox4117*, or *loxH* site.
67. The composition of claim 65 wherein the lox recombinase site is a *loxP*, *loxP2*, *loxP3*, *loxP23*, *loxP511*, *loxB*, *loxC2*, *loxL*, *loxR*, *lox486*, *lox4117*, or *loxH* site.
68. The composition of claim 64, wherein the amino acid encoding region is a member of a nucleic acid library.

## II. REMARKS

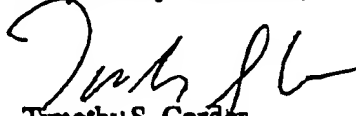
The claims in this preliminary amendment do not add new matter to the application and their entry is therefore respectfully requested. Support for the claims may be found throughout the Specification and at least in Example 3 found on page 47.

## IV. CONCLUSION

Applicants respectfully submit that the present application and all claims are in condition for immediate allowance and early notice to such effect is earnestly solicited. If, in the opinion of the Examiner, a phone call may help expedite prosecution of this application, the Examiner is invited to contact the undersigned representative at (512) 542-8446.

It is believed that no fee is due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Assistant Commissioner is authorized to deduct said fees from Vinson & Elkins L.L.P. Deposit Account No. 22-0365/BAY136/4-10CIP/36000.

Respectfully submitted,



Timothy S. Corder  
Reg. No. 38,414  
Agent for Applicant

Vinson & Elkins L.L.P.  
2300 First City Tower  
1001 Fannin  
Houston, Texas 77002-6760  
512/542-8446

Date: October 3, 2002

P-18  
STIPX  
PRDSX

CAUSE NO. 2001-61352

BAYLOR COLLEGE OF MEDICINE and  
BCM TECHNOLOGIES, INC.,

PLAINTIFFS/COUNTERCLAIM DEFENDANTS,

v.

CLONTECH LABORATORIES, INC.,

DEFENDANT/COUNTERCLAIM PLAINTIFF,

INVITROGEN CORPORATION,

ADDITIONAL COUNTERCLAIM DEFENDANT, §

IN THE DISTRICT COURT

HARRIS COUNTY, TEXAS

133<sup>RD</sup> JUDICIAL DISTRICTFILED  
CHARLES BACARISSE  
District Clerk

OCT 29 2002

By  Deputy  
Harris County, TexasSTIPULATED PROTECTIVE ORDER

Whereas pretrial discovery in this action will necessarily involve the disclosure of trade secrets or confidential research, development, or commercial information of both parties and of non-parties from whom discovery may be sought; and

Whereas the parties have in good faith conferred and have agreed upon the terms of a Protective Order and for good cause shown; therefore

The parties stipulate, pursuant to Texas Rule of Civil Procedure 192.6, subject to the approval of the Court, to the following Protective Order:

1. **Scope of Protection.**

1.1 This Protective Order shall govern any record of information, designated pursuant to ¶ 2 of this Protective Order, produced in this action, including all designated deposition testimony, all designated testimony taken at a hearing or other proceeding, interrogatory answers, documents and

EXHIBITS BEING INDEXED  
This instrument is of best quality  
and not suitable for photographic  
reproduction; and/or alterations were  
present at the time of indexing



other discovery materials, whether produced informally or in response to interrogatories, requests for admissions, requests for production of documents or other formal method of discovery.

1.2 This Protective Order shall also govern any designated record of information produced in this action pursuant to required disclosures under any Texas State procedural rule or Harris County District Court local rule, and any supplementary disclosures thereto.

1.3 This Protective Order shall apply to the parties and any nonparty from whom discovery may be sought and who desires the protection of this Protective Order.

## **2. Designation.**

2.1 Each party shall have the right to designate as confidential and subject to this Protective Order any information produced by it in this action which contains, reflects, or otherwise discloses confidential technical, business or financial information ("CONFIDENTIAL information"). This designation shall be made by stamping or otherwise labeling each page or thing containing confidential information with the legend CONFIDENTIAL prior to its production or, if inadvertently produced without such legend, by furnishing written notice to the receiving party that the information shall be considered confidential under this Protective Order. The parties will use reasonable care to avoid designating any documents or information CONFIDENTIAL that are generally available to the public.

2.2 Each party shall have the right to designate as restricted to review by those categories of individuals listed in ¶ 4.1, excluding ¶¶ 4.1(d), 4.1(e) and 4.1(f), and subject to this Protective Order any information produced in this action which contains, reflects, or otherwise discloses trade secrets, current research and development information or competitively sensitive information, ("OUTSIDE ATTORNEY'S EYES ONLY information"). To the extent that

material is marked **OUTSIDE ATTORNEY'S EYES ONLY**, such material shall be revealed to or used by limited categories of individuals, as provided for in ¶ 4.2, and shall not be communicated in any manner, either directly or indirectly, to any person or entity not permitted disclosure pursuant to this Protective Order. Any copies of such material, abstracts, summaries or information derived therefrom, and any notes or other records regarding the contents thereof, shall also be deemed **OUTSIDE ATTORNEY'S EYES ONLY**, and the same terms regarding confidentiality of these materials shall apply as apply to the originals. Use of this highly restrictive designation is limited to information of the highest, competitive sensitivity. The parties will use reasonable care to avoid designating any documents or information **OUTSIDE ATTORNEY'S EYES ONLY** for which the designating party does not have a good faith belief that the documents or information satisfy the criteria set forth in this ¶ 2.2. **OUTSIDE ATTORNEY'S EYES ONLY** information shall be used only for purposes directly related to this action, and for no other purpose whatsoever, except by consent of all of the parties or order of the Court.

2.3 To the extent that either party has, prior to the date that this Order is entered, produced to the other side materials that the producing party has marked with any confidentiality designation, all such materials shall be considered to have been designated under this Order as **OUTSIDE ATTORNEY'S EYES ONLY** unless otherwise agreed by the Parties.

### 3. Limit On Use And Disclosure Of Designated Information.

3.1 Each party and all persons bound by the terms of this Protective Order shall use any information or document governed by this Protective Order only in connection with the prosecution or defense of this action, except by consent of the parties or order of the Court. No party or other

person shall disclose or release to any person not authorized under this Protective Order any information or document governed by this Protective Order for any purpose, or to any person authorized under this Protective Order for any other purpose.

3.2 It is, however, understood that counsel for a party may give advice and opinions to his or her client based on his or her evaluation of designated confidential information received by the party, provided that such rendering of advice and opinions shall not reveal the content of such information except by prior written agreement with counsel for the producing party.

3.3 The attorneys of record for the parties and other persons receiving information governed by this Protective Order shall exercise reasonable care to insure that the information and documents governed by this Protective Order are (a) used only for the purposes specified herein, and (b) disclosed only to authorized persons.

#### 4. Disclosure Of Confidential Material.

4.1 Documents or information designated CONFIDENTIAL shall be disclosed by the recipient thereof, on a need-to-know basis, only to:

a. the attorneys who are actively involved in this action and who are partners or associates of the following law firms, which are trial counsel or attorneys of record for the parties, and their employees: (i) Bracewell & Patterson LLP; (ii) Patton Boggs LLP; and (iii) Vinson & Elkins LLP.

b. the Court and Court personnel, as provided in ¶ 12;

c. consultants or experts and their staffs retained by the parties or their attorneys for purposes of this action, who are agreed upon by the parties pursuant to ¶ 6, who are not employees or otherwise affiliated with either of the parties (except persons scheduled to be deposed

by either of the parties pursuant to Rule 30(b)(6), Fed.R.Civ.P.), and who first agree to be bound by the terms of this Protective Order:

d. Clontech's (or its successor-in-interest) in-house counsel not involved in the preparation or prosecution of patent applications and/or competitive decision making, provided that each individual must first agree to be bound by the terms of this Protective Order and shall be given access to such documents and information only at the offices of his respective attorneys of record as set forth in § 4.a. Copies of such documents and information are not given to any of the people to be taken off the premises of the party's counsel;

e. Baylor's in-house counsel not involved in the preparation or prosecution of patent applications and/or competitive decision-making, provided that each individual must first agree to be bound by the terms of this Protective Order and shall be given access to such documents and information only at the offices of his respective attorneys of record as set forth in § 4.a. Copies of such documents and information are not given to any of the people to be taken off the premises of the party's counsel;

f. Invitrogen's in-house counsel not involved in the preparation or prosecution of patent applications and/or competitive decision-making, provided that each individual must first agree to be bound by the terms of this Protective Order and shall be given access to such documents and information only at the offices of his respective attorneys of record as set forth in § 4.a. Copies of such documents and information are not given to any of the people to be taken off the premises of the party's counsel;

g. court reporters employed in connection with this action; and

h. outside copying and computer services necessary for document handling, and other litigation support personnel (e.g., graphic designers and animators).

4.2 Documents or information designated OUTSIDE ATTORNEY'S EYES ONLY shall be disclosed by the recipient thereof, on a need-to-know basis, to those categories of individuals listed in ¶ 4.1, excluding ¶¶ 4.1(d), 4.1(e) and 4.1(f).

## 5. Redaction.

Counsel for a party producing documents may mask ("redact") material deemed exempt from discovery because it is protected from disclosure under the attorney-client privilege or work product immunity afforded by Rule 26(b), Fed.R.Civ.P. and/or Texas Rule of Civil Procedure. However, any document from which material is masked must identify in the masked area that masking or redaction has occurred. The reason for any such masking must be stated on a log to be provided within thirty (30) days after the production of the documents. Sufficient information regarding the masked material must be provided to the other party to enable it to evaluate the legitimacy of the asserted privilege or immunity. The parties reserve the right to pursue categories for redaction in addition to those identified above, by either consent of the parties or order of the Court, to be addressed on a case-by case basis.

## 6. Identification Of Experts.

6.1 If any party desires to disclose information designated CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY to any expert or consultant pursuant to ¶ 4 above, it must first identify in writing to the attorneys for the producing party each such expert or consultant. The attorney for the producing party shall have five (5) business days from receipt of such notice to object to disclosure of such information to any of the experts or consultants so identified.

6.2 Such identification shall include the full name and professional address and/or affiliation of the proposed expert or consultant, an up-to-date curriculum vitae identifying at least all other present and prior employments or consultancies of the expert or consultant in the field, and a list of the cases in which the expert or consultant has testified at a deposition or at trial within the last four years. The parties shall attempt to resolve any objections informally. If the objections cannot be resolved, the party seeking to disclose the CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY information to the expert or consultant may move the Court for an Order allowing the disclosure. In the event objections are made and not resolved informally, disclosure of information to the expert or consultant shall not be made except by Order of the Court (or to any limited extent upon which the parties may agree).

**7. Agreement Of Confidentiality.**

In no event shall any information designated CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY be disclosed to any person authorized pursuant to ¶ 4, other than (a) the Court and Court personnel, (b) the parties' attorneys (excluding in-house counsel) and their authorized secretarial and legal assistant staffs, (c) court reporters, and (d) outside copying and computer services necessary for document handling, until such person has executed a written Confidentiality Undertaking (in the form set forth in Exhibit A hereto) acknowledging and agreeing to be bound by the terms of this Protective Order. Copies of such Confidentiality Undertakings shall be promptly served on the producing party.

## **8. Related Documents.**

Information designated CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY shall include (a) all documents, copies, extracts, and complete or partial summaries prepared from or containing such information; (b) portions of deposition transcripts and exhibits thereto which contain or reflect the content of any such documents, copies, extracts, or summaries; (c) portions of briefs, memoranda or any other papers filed with the Court and exhibits thereto which contain or reflect the content of any such documents, copies, extracts, or summaries; (d) deposition testimony designated in accordance with ¶ 9; and (e) testimony taken at a hearing or other proceeding that is designated in accordance with ¶ 10.

## **9. Designation Of Deposition Transcripts.**

9.1 Deposition transcripts, or portions thereof, may be designated as subject to this Protective Order either (a) at the time of such deposition, in which case the transcript of the designated testimony shall be marked by the reporter with the appropriate legend (see ¶ 2.1) as the designating party may direct, or (b) within thirty (30) days following taking of the deposition by providing written notice to the reporter and all counsel of record, in which case all counsel receiving such notice shall mark the copies or portions of the designated transcript in their possession or under their control as directed by the designating party.

9.2 All deposition transcripts not previously designated shall be deemed to be, and shall be treated as, OUTSIDE ATTORNEY'S EYES ONLY for a period of thirty (30) days after the taking of the deposition, and the transcript shall not be disclosed by a non-designating party to persons other than those persons named or approved according to ¶ 4.

9.3 The designating party shall have the right to exclude from a deposition, before the taking of testimony which the designating party designates CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY and subject to this Protective Order, all persons other than those persons previously qualified to receive such information pursuant to ¶ 4.

#### **10. Designation Of Hearing Testimony Or Argument.**

With respect to testimony elicited during hearings and other proceedings, whenever counsel for any party deems that any question or line of questioning calls for the disclosure of CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY information, counsel may designate on the record prior to such disclosure that the disclosure is subject to confidentiality restrictions. Whenever matter designated CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY is to be discussed in a hearing or other proceeding, any party claiming such confidentiality may ask the Court to have excluded from the hearing or other proceeding any person who is not entitled under this Order to receive information so designated.

#### **11. Disclosure To Author Or Recipient.**

Notwithstanding any other provisions of this Order, nothing herein shall prohibit counsel for a party from disclosing a document containing information designated CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY to any person which the document clearly identifies as an author, addressee, or carbon copy recipient of such document, or to any current employee of the producing party. During deposition or trial testimony, counsel may disclose documents produced by a party to current employees and officers of the producing party. And regardless of such designation pursuant to this Protective Order, if a document or testimony makes reference to the actual or alleged



conduct or statements of a person who is a potential witness, counsel may discuss such conduct or statements with such witness without revealing any portion of the document or testimony other than that which specifically refers to such conduct or statement, and such discussion shall not constitute disclosure in violation of this Protective Order.

**12. Designation Of Documents Under Seal**

Any information designated OUTSIDE ATTORNEY'S EYES ONLY, if filed with the Court, shall be filed under seal and shall be made available only to the Court and to persons authorized by the terms of this Protective Order. The party filing any paper which reflects, contains or includes any OUTSIDE ATTORNEY'S EYES ONLY information subject to this Protective Order shall file such paper in a sealed envelope, or other appropriately sealed container, which indicates the title of the action, the party filing the materials, the nature of the materials filed, the appropriate legend (see ¶ 2.1), and a statement substantially in the following form:

**This envelope contains documents subject to a Protective Order of the Court. It should be opened only by the Court. Its contents should not be disclosed, revealed or made public except by Order of the Court or written agreement of the parties.**

**13. Confidentiality Of Party's Own Documents.**

No person may disclose, in public or private, any designated information of another party except as provided for in this Protective Order, but nothing herein shall affect the right of the designating party to disclose to its officers, directors, employees, attorneys, consultants or experts, or to any other person, its own information. Such disclosure shall not waive the protections of this Protective Order and shall not entitle other parties or their attorneys to disclose such information in violation of it, unless by such disclosure of the designating party the information becomes public

knowledge (see ¶ 16). Similarly, the Protective Order shall not preclude a party from showing its own information to its officers, directors, employees, attorneys, consultants or experts, or to any other person, which information has been filed under seal by the opposing party.

**14. Other Protections.**

14.1 No person shall use any CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY information, or information derived therefrom, for purposes other than the prosecution or defense of this action, including without limitation, for purposes of preparing, filing or prosecuting any patent application, continuation or divisional patent application, reissue patent application or request for re-examination.

14.2 Any party may mark any document or thing containing CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY information as an exhibit to a deposition, hearing or other proceeding and examine any witness thereon qualified under the terms of this Protective Order to have access to such designated material.

**15. Challenge To Confidentiality.**

15.1 This Protective Order shall not preclude any party from seeking and obtaining, on an appropriate showing, such additional protection with respect to the confidentiality of documents or other discovery materials as that party may consider appropriate. Nor shall any party be precluded from (a) claiming that any matter designated hereunder is not entitled to the protections of this Protective Order, (b) applying to the Court for an Order permitting the disclosure or use of information or documents otherwise prohibited by this Protective Order, or (c) applying for a further Order modifying this Protective Order in any respect. No party shall be obligated to challenge the

propriety of any designation, and failure to do so shall not preclude a subsequent challenge to the propriety of such designation.

15.2 On any motion challenging the designation of any information, the burden of proof shall lie with the producing party to establish that the information is, in fact, CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY information. If a party seeks declassification or removal of particular items from a designation on the ground that such designation is not necessary to protect the interests of the party wishing the designated information, the following procedure shall be utilized:

a. The party seeking such declassification or removal shall give counsel of record for the other party written notice thereof by facsimile, with confirmation by mail or by personal delivery, specifying the designated information as to which such removal is sought and the reasons for the request; and

b. If, after conferring, the parties cannot reach agreement concerning the matter within five (5) business days after the delivery and receipt of the notice, then the party requesting the declassification or removal of particular items may file and serve a motion for a further Order of this Court directing that the designation shall be so removed.

#### 16. Prior Or Public Knowledge.

This Protective Order shall not apply to information that, prior to disclosure, is public knowledge, and the restrictions contained in this Protective Order shall not apply to information that is, or after disclosure becomes, public knowledge other than by an act or omission of the party to whom such disclosure is made, or that is legitimately and independently acquired from a source not subject to this Protective Order.

**17. Limitation Of Protective Order.**

This Protective Order is not intended to address discovery objections to produce, answer, or respond on the grounds of attorney-client privilege or work product immunity, or to preclude either party from seeking further relief or protective orders from the Court as may be appropriate under the Federal Rules of Civil Procedure.

**18. Other Proceedings.**

18.1 By entering this order and limiting the disclosure of information in this case, the court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who may be subject to a motion to disclose another party's CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY information pursuant to this order shall promptly notify that party of the motion so that it may have an opportunity to appear and be heard on whether such information should be disclosed.

**19. Inadvertent Disclosure Of Work Product Or Privileged Information: Procedure And Waiver.**

19.1 The producing party shall promptly notify the receiving party in writing in the event of an inadvertent production of documents subject to work product immunity or the attorney-client privilege after the producing party learns of such inadvertent production.

19.2 If prompt notification is made and the producing party establishes the circumstances surrounding the document's inadvertent production, such inadvertently produced document and all copies thereof shall be returned to the producing party or destroyed, upon request.

19.3 No use shall be made of such documents during deposition or at trial, nor shall they be shown to anyone who was not given access to them prior to the request to return or destroy them.

19.4 If, after conferring, the parties are unable to reach a satisfactory agreement within five (5) business days of receipt of the request to return or destroy them, the producing party may move the Court regarding the matter within ten (10) business days after conferring.

19.5 The non-producing party shall not disclose the document for which the belated claim of immunity or privilege is being made to any person, other than those persons who have had it in their possession prior to receipt of notification from the producing party, until the expiration of the ten (10) day period identified in ¶ 19.4 or, if a motion to the Court is submitted, until disposition of that motion. Upon being notified by the producing party pursuant to ¶ 19.1, counsel for the non-producing party shall use his or her best efforts to retrieve all copies of the documents at issue.

19.6 Following expiration of the fifteen (15) day term, nothing in this Protective Order shall preclude either party from moving the Court for return or destruction of later discovered, inadvertently produced work product immunity or attorney-client privileged documents.

## 20. Non-Party Material.

The terms of this Protective Order, as well as the terms of any protective order that may be entered into between a discovering party and third party for the production of information to the discovering party, are applicable to CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY information provided by a non-party. Information provided by a non-party in connection with this action and designated CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY, pursuant to the terms of this Protective Order shall be protected by the remedies and relief provided by this Protective Order.

**21. Return Of Designated Information.**

Upon final termination of this action, unless otherwise agreed to in writing by an attorney of record for the designating party, each party shall assemble and return, or certify destruction of, all materials containing information designated CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY, including all copies, extracts and summaries thereof, to the party from whom the designated material was obtained, except that (a) any documents or copies which contain, constitute or reflect attorney's work product or attorney-client privilege communications, and (b) archive copies of pleadings, motion papers, deposition transcripts, correspondence and written discovery responses may be retained by counsel.

**22. Waiver Or Termination Of Order.**

No part of the restrictions imposed by this Protective Order may be waived or terminated, except by written stipulation executed by counsel of record for each designating party, or by an Order of the Court for good cause shown. The restrictions provided for herein shall not terminate upon the conclusion of this action, but shall continue until further Order of this Court.

**23. Modification Of Order; Prior Agreements.**

This Protective Order may be modified, and any matter related to it may be resolved, by written stipulation of the parties without further Order of the Court. This Protective Order supersedes any agreements between the parties regarding the confidentiality of particular information entered into before the date of this Protective Order.

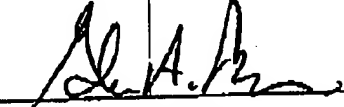
24. **Section Captions.**

The title captions for each section of this Protective Order are for convenience only and are not intended to affect or alter the text of the sections or the substance of the Order.

Dated: August \_\_, 2002

**BRACEWELL & PATTERSON LLP**

By: \_\_\_\_\_

  
Glenn A. Ballard, Jr.  
Attorney-in-Charge  
Texas State Bar No. 01650200

711 Louisiana Street, Suite 2900  
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**ATTORNEYS FOR  
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*Of Counsel:*

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APPROVED AS TO FORM:

Dated: August 28, 2002

*afh*

VINSON & ELKINS LLP

By: 

David P. Blanke  
Attorney-in-Charge  
Tracey Davies  
Adam V. Floyd

600 Congress Avenue, Suite 2700  
Austin, Texas 78701-3248

ATTORNEYS FOR  
BAYLOR COLLEGE OF MEDICINE,  
BCM TECHNOLOGIES, INC., and  
INVITROGEN CORPORATION

Of Counsel:

Stuart J. Ford

Jason M. Powers


VINSON & ELKINS LLP

1001 Fannin Street, Suite 2300

Houston, Texas 77002-6760

IT IS SO ORDERED:

*Signed*  
Dated: August 28, 2002

  
UNITED STATES DISTRICT JUDGE PRESIDING



CAUSE NO. 2001-61352

BAYLOR COLLEGE OF MEDICINE and  
BCM TECHNOLOGIES, INC.,

PLAINTIFFS/COUNTERCLAIM DEFENDANTS,

v.

CLONTECH LABORATORIES, INC.,

DEFENDANT/COUNTERCLAIM PLAINTIFF,

INVITROGEN CORPORATION,

ADDITIONAL COUNTERCLAIM DEFENDANT,

IN THE DISTRICT COURT

HARRIS COUNTY, TEXAS

133<sup>RD</sup> JUDICIAL DISTRICT

**CONFIDENTIALITY UNDERTAKING**

I certify that I have read the Stipulated Protective Order in this action and that I fully understand the terms of the Order. I recognize that I am bound by the terms of that Order, and I agree to comply with those terms. I hereby consent to the personal jurisdiction of the Harris County District Court for any proceedings involving the enforcement of that Order.

EXECUTED this \_\_\_\_\_ day of \_\_\_\_\_, 2002.

\_\_\_\_\_  
Name

\_\_\_\_\_  
Affiliation

\_\_\_\_\_  
Business Address

**EXHIBIT A**

**EXPEDITED PROCEDURE REQUESTED  
PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Elledge et al.	)	Examiner: James S. Ketter
	)	
USSN: 09/122,384	)	Art Unit: 1636
	)	
For: Rapid Subcloning Using Site-Specific Recombination	)	Filed: July 24, 1998
	)	

**PROTEST AGAINST PENDING APPLICATION UNDER 37 C.F.R. § 1.291**

Honorable Commissioner for Patents  
Mail Stop Petitions  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Clontech Laboratories, Inc. ("Clontech") hereby petitions the Commissioner to initiate a protest against pending application number 09/122,384 under 37 C.F.R. § 1.291.

**I. SUBJECT MATTER DISCLOSED IN U.S. SERIAL NO. 09/122,384 IS THE SUBJECT MATTER OF LITIGATION**

Clontech is in litigation against BCM Technologies, Inc. and Baylor College of Medicine (collectively "BCM"), who are believed to be the assignee of USSN 09/122,384 ("the '384 application") over an alleged theft of trade secrets. The case is in the Texas 133<sup>rd</sup> Judicial District Court in Harris County, Texas, Cause No. 2001-61352.

Clontech repeatedly requested all documents concerning U.S. Patent No. 5,851,808 ("the '808 patent"), the patent that issued from the parent application to the '384 application, which document requests encompass any continuations and continuations-in-part thereof. Clontech

again explicitly requested all documents related to any continuation applications following the April 14, 2003 deposition of Charles Lipsey (the April 14, 2003 letter requesting such documents is attached as Ex. 1 hereto), during which BCM's questioning implied that one or more continuation applications may be pending. BCM has repeatedly ignored such demands and failed to provide such documents until recently, after the close of discovery in the pending litigation. BCM's conduct is the subject of a motion to compel in the Texas Court.

On May 6, 2003, after the close of discovery, litigation counsel for BCM belatedly provided a letter to Clontech enclosing a Notice of Allowability of USSN 09/122,384, which was mailed in late April (Ex. 2 hereto). BCM also provided other documents to Clontech on May 16 and 17, 2003, indicating information disclosed to the Office.

The information BCM provided to Clontech does not indicate that BCM alerted the Office to the case *Baylor College of Medicine et al. v. Clontech Laboratories, Inc. v. Invitrogen Corp.* case in the Texas 133<sup>rd</sup> Judicial Court in Harris County, Texas. (A copy of Plaintiff's First Amended Petition is attached hereto as Ex. 3). This case is related to the subject matter of the '384 application and the '808 patent. Nor does the information provided by BCM indicate that BCM alerted the Office to the declaratory judgment action filed in the U.S. District Court for the Southern District of Texas on January 4, 2002, alleging *inter alia*, the invalidity and non-infringement of the '808 patent. (A copy of the Complaint For Declaratory Judgment is attached hereto as Ex. 4). The latter federal case was only recently dismissed on April 7, 2003 (Ex. 5), as a result of BCM's motion to dismiss along with its Covenant Not To Assert The '808 Patent (Ex. 6), which were also not brought to the attention of the Office.

Under 37 C.F.R. § 1.56, applicants and applicants' representatives must disclose (1) the existence of litigation and (2) any material information arising from that litigation related to the

subject matter of the patent application, including, for example, deposition testimony. *See, e.g.*, MPEP 2001.06(c); *Environ Products v. Total Containment, Inc.*, 43 U.S.P.Q. 2d 1288 (E.D. Pa. 1997); *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 68 F. Supp.2d 508 (D.N.J. 1999).

The documents BCM recently provided to Clontech from the PTO prosecution include disclosures of some prior art to the Office, but do not include any disclosure of the ongoing litigation and do not include any disclosure of critical admissions that occurred in depositions taken during discovery. The submitted documents also do not include any disclosure of the dismissed litigation and covenant not to assert the '808 patent.

## **II. THIS PROTEST INVOLVES INFORMATION THAT CANNOT BE ADEQUATELY ADDRESSED WITH REEXAMINATION**

Our request for a Protest can only be addressed before issuance because the standard and type of prior art that may be considered will change after issuance. During examination, the Office need only show by a preponderance of the evidence that an application is unpatentable. Once a U.S. patent is issued, any challenge must be supported by clear and convincing evidence. While an issued U.S. patent can be reexamined, a reexamination can only consider patents and printed publications and only address issues arising under sections 102 or 103 of Title 35. BCM should not be permitted to benefit from its refusal to disclose information to the USPTO and to Clontech in a timely manner.

Clontech is bound by a protective order in the ongoing Texas litigation. This protective order bars Clontech from disclosing BCM information and deposition transcripts if BCM has designated them as confidential. BCM has utilized this protective order to designate much of the information disclosed as confidential and has designated all of its witnesses' deposition

testimony as confidential, except that of Dr. Liu. Consequently, Clontech cannot describe any admissions that might be present in other depositions that have occurred, including the depositions of Drs. Elledge and Kreuzer and Ms. Li. Nevertheless, Clontech can disclose that the deposition transcript which BCM did not designate as confidential – that of Dr. Liu -- contains admissions that are material to the patentability of the claims that were provided in the preliminary amendment of October 3, 2002. Claim numbers corresponding to those claims have now been allowed.

The deposition of Dr. Liu admits that at the time of filing of the application that led to the '808 patent (and therefore, necessarily before filing the '384 application therefrom), GST fusion proteins were known and the Cre enzyme was known:

Q: Okay. Now, GST fusion proteins were known in the art prior to your work, correct?

A: Correct.

Q. And the Cre enzyme itself was known in the art prior to your work, correct?

A. Correct.

Q. And am I correct in understanding that the Cre recombinases [sic recombinase], the Cre enzyme, its ability to recombine loxP site [sic sites] was also known in the art, correct?

A. Correct.

(Liu Dep. at 15:23-16:8, Ex. 7).

These admissions appear material to the patentability of for example claims 43, 46, 48, 49, 52-54, 56 and 63 as those claims appear in the Preliminary Amendment that BCM disclosed to Clontech. These claim numbers are those that appear to correspond to the allowed claims on the Notice of Allowability. (Ex. 1).

While Clontech cannot provide information marked confidential to the Office, BCM can provide this information to the PTO. This information can be supplied as part of BCM's Duty of Disclosure under Rule 1.56, or it can be provided in response to a direct request from the Examiner under 37 C.F.R. § 1.105.

The review under 37 C.F.R. § 1.291 represents the PTO's last opportunity to consider information contained in the deposition transcripts. Once the 09/122,384 patent issues, the PTO will not be able to provide any meaningful review of the deposition transcript admissions. As indicated by Assistant Deputy Commissioner Kunin, "[t]he PTO has an obligations to issue patents that meet the statutory requirements for patentability." *Blacklight Power, Inc. v. Rogan*, 295 F.3d 1269, 1271 (Fed. Cir. 2002) (affirming the PTO's decision to cancel issuance of a patent after allowance and after the issue fee was paid). Moreover, the PTO is vested with broad "latitude to withdraw an application from issue without a final determination of unpatentability when the exigencies of time do not allow for such determination." *Id.* at 1272.

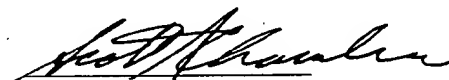
### **III. THE PTO SHOULD PERMIT THE INITIATION OF A PROTEST OR STAY ISSUANCE OF A PATENT ON THE '384 APPLICATION**

The PTO should initiate a Protest, based on the failure of BCM to alert the agency to ongoing litigation related to the '384 application and the failure of BCM to provide the PTO with material deposition admissions. In the alternative, the PTO should stay issuance of the '384 application until the Judge in the Texas 133<sup>rd</sup> Judicial District Court rules on Clontech's Motion to De-designate Certain Deposition Admissions Material to the Patentability Determination of Baylor Patent Application Claims and permits the PTO Examiner to review the deposition testimony. Clontech is presently preparing a motion to de-designate the transcripts or portions thereof that contain admissions material to the patentability of the '384 application. This motion will be submitted to the Judge, who will determine if this information can be provided to the PTO to permit the PTO to perform its mission.

This Protest has been served upon applicants via their representative in accordance with 37 CFR § 1.248 as well as being filed in duplicate with the PTO. Proof of service is attached as Exhibit 8 hereto.

The U.S. Patent and Trademark Office is hereby authorized to charge any fees that may be required in conjunction with this submission to Deposit Account Number 50-2228.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Scott A. Chambers", written over a horizontal line.

Scott A. Chambers  
Reg. No. 37,573

PATTON BOGGS, LLP  
8484 Westpark Drive, 9<sup>th</sup> Floor  
McLean, Virginia 22102  
Phone: (703) 744-8000  
Fax: (703) 744-8001

## CERTIFICATE OF SERVICE

I hereby certify that on May 20, 2003 I caused to be delivered by fax and FED EX a copy of **PROTEST AGAINST PENDING APPLICATION UNDER 37 C.F.R. § 1.291** and exhibits 1-8 thereto relating to USSN 09/122,384, addressed to the attorney of record in that matter as follows:

Timothy S. Corder  
Vinson & Elkins LLP  
The Terrace 7  
2801 Via Fortuna, Suite 100  
Austin, Texas 78746-7568  
Phone: (512) 542-8400  
Fax: (512) 542-8612

I declare under penalty of perjury that the foregoing is true and correct.

A handwritten signature in cursive script, appearing to read "Timothy S. Corder", written over a horizontal line.

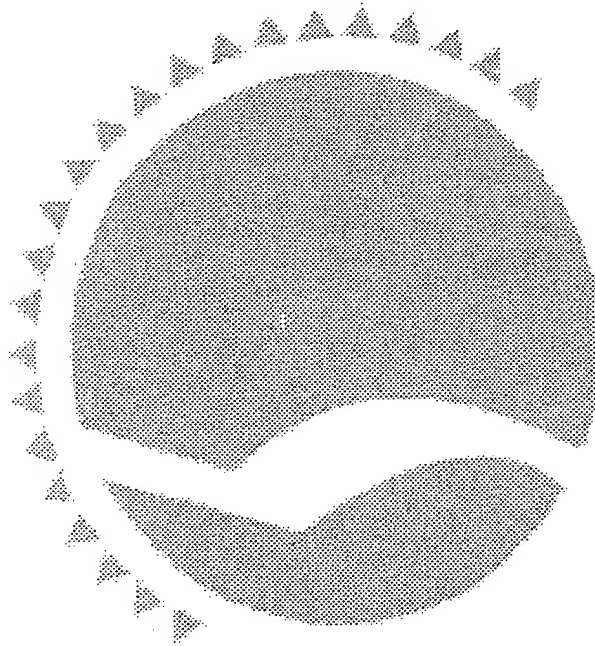


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**ORAL DEPOSITION OF QINGHUA LIU**

**February 7, 2003**

---



CONDENSED TRANSCRIPT AND CONCORDANCE  
PREPARED BY:

**Sunbelt Reporting & Litigation Services**  
**(713) 667-0763 Houston**  
**(214) 747-0763 Dallas**

## Page 1

1 CAUSE NO. 2001-61352  
 2 BAYLOR COLLEGE OF MEDICINE ) IN THE DISTRICT COURT OF  
 3 and BCM TECHNOLOGIES, INC.. )  
 4 )  
 5 Plaintiffs/Counter-defendants.)  
 6 )  
 7 VS. )  
 8 )  
 9 CLONTECH LABORATORIES, INC.. ) HARRIS COUNTY, T E X A S  
 10 )  
 11 Defendant/Counter-plaintiff. )  
 12 )  
 13 VS. )  
 14 )  
 15 INVITROGEN CORPORATION. )  
 16 )  
 17 Additional Counterclaim )  
 18 Defendant. ) 133RD JUDICIAL DISTRICT  
 19 \*\*\*\*\*  
 20 ORAL DEPOSITION OF  
 21 QINGHUA LIU  
 22 February 7, 2003  
 23 \*\*\*\*\*  
 24 Reported By: Taye J. Clark  
 25 Job No. 39664

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17	3 United States Patent No. 005851808A	18
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## Page 3

1 ORAL DEPOSITION OF  
 2 QINGHUA LIU, produced as a witness at the instance of  
 3 the DEFENDANT/COUNTER-PLAINTIFF, and duly sworn, was  
 4 taken in the above-styled and numbered cause on the 7th  
 5 day of February, from 9:14 a.m. to 10:58 a.m., before  
 6 Taye J. Clark, CSR in and for the State of Texas,  
 7 reported at the offices of Patton Boggs, LLP, 2001 Ross  
 8 Avenue, Suite 3000, Dallas, Texas 75201, pursuant to  
 9 the Texas Rules of Civil Procedure and the provisions  
 10 stated on the record or attached hereto.  
 11  
 12 A P P E A R A N C E S  
 13  
 14 FOR THE PLAINTIFFS/COUNTER-DEFENDANTS:  
 15 MS. M. MICHELLE MULLER, PH.D.  
 16 Vinson & Elkins  
 17 The Terrace 7  
 18 2801 Via Fortuna, Suite 100  
 19 Austin, Texas 78746-7568  
 20  
 21 FOR THE DEFENDANT/COUNTER-PLAINTIFF:  
 22 MR. MARC R. LABGOLD, PH.D.  
 23 Patton Boggs, LLP  
 24 8484 Westpark Drive  
 25 McLean, Virginia 22102

## Page 4

1 PRELIMINARY PROCEEDINGS  
 2 THE REPORTER: Going on the record at  
 3 9:14 a.m.  
 4 QINGHUA LIU,  
 5 having been first duly sworn, testified as follows:  
 6 THE REPORTER: By the Rules?  
 7 MR. LABGOLD: Yes.  
 8 THE REPORTER: Do you want to read and  
 9 sign?  
 10 MS. MULLER: Yes.  
 11 MR. LABGOLD: In front of any Notary is  
 12 fine.  
 13 EXAMINATION  
 14 QUESTIONS BY MR. MARC R. LABGOLD:  
 15 Q Good morning, Dr. Liu.  
 16 A Good morning to you, too.  
 17 Q Have you ever been deposed before?  
 18 A No.  
 19 Q Okay. Just so you understand, I'm going to ask  
 20 you some questions, I'm going to show you some  
 21 documents. Hopefully my questions will be clear enough  
 22 that you'll understand.  
 23 If you don't understand the question, just  
 24 ask and I'll try to clarify.  
 25 Your counsel may have certain objections.

## Page 5

1 She'll say, "Objection." The first time she does, I  
2 guarantee you you'll sit there and turn around and look  
3 at her and wait for something else. That's all it is,  
4 she's noting an objection for the record.

5 Unless she instructs you not to answer,  
6 I'll expect an answer to the best of your ability.

7 By whom are you currently employed?

8 A U.T. Southwestern in Dallas.

9 Q Okay. And what's your position there?

10 A Post doctoral fellow.

11 Q In whose lab?

12 A Dr. Xiaodong Wang.

13 Q And what type of work are you doing?

14 A Biochemistry.

15 Q On what type of project?

16 A RNA Interference.

17 Q And how long have you been in your current  
18 position?

19 A Two years.

20 Q And prior to that, am I correctly understanding  
21 you were at Baylor?

22 A Yes.

23 Q And for the entire time you were at Baylor,  
24 were you in Dr. Elledge's lab?

25 A Yes.

## Page 6

1 Q Now, did you prepare -- did you do anything to  
2 prepare for your deposition here today?

3 A You mean the deposition document?

4 Q Did you -- did you meet with your attorneys?

5 A Yes.

6 Q And who did you meet with?

7 A I meet with Michelle and Tracy.

8 Q Okay. And for how long did you meet?

9 A About two --

10 MS. MULLER: I'm going to object on the  
11 basis of privilege.

12 MR. LABGOLD: That's not a privilege.

13 You want me to show you transcripts from  
14 yesterday where I went through the same thing?

15 It's not privileged that you met, it's not  
16 privileged where you met, it's not privileged how long  
17 you met. I'm allowed to ask him as I did for the last  
18 few depositions what documents he reviewed. I'm allowed  
19 to ask if anything refreshes his recollection.

20 I can ask him what he discussed during  
21 those meetings and you can object and instruct him not  
22 to answer, but other than that, I'm entitled to an  
23 answer.

24 Q (By Mr. Labgold) How long did you meet?

25 MS. MULLER: Well, I'm going to have to

## Page 7

1 review that, and if I'm incorrect on that, I will look  
2 at it, but for the moment I'm going to object on the  
3 basis of privilege.

4 MR. LABGOLD: Well, it's not worth my  
5 time, but I will tell you this -- no.

6 Q (By Mr. Labgold) Did you review any documents  
7 during your preparation?

8 A No.

9 Q Other than your meeting with your counsel at  
10 some unidentified undisclosed location -- the vice  
11 president may have been there with you but I won't ask  
12 that because that may also be privileged -- did you do  
13 anything else to prepare to be able to testify here  
14 today?

15 A No.

16 Q Have you spoken to Dr. Elledge anytime in the  
17 past year about the subject of the Univector System or  
18 this laboratory -- or this litigation?

19 A Yes.

20 Q And what were -- what did you discuss with Dr.  
21 Elledge?

22 A I call him, ask him if he knows I have to talk  
23 to you, and he said he knew about it, it's fine.

24 Q Did he tell you that he had had a deposition?

25 A Yes.

## Page 8

1 Q Did he tell you what questions were asked  
2 during that deposition?

3 A No.

4 Q Did you discuss anything else concerning the  
5 deposition or just asking him if it was okay to do a  
6 deposition?

7 A He said, "Answer the question to your best  
8 knowledge, do not make any guess."

9 Q Anything else?

10 A No.

11 Q Now, if I understand correctly, you were one of  
12 the people who contributed to the development of the  
13 Univector System, correct?

14 A Yes.

15 Q And you have prepared a paper which was  
16 published, disclosed in that system, correct?

17 A Yes.

18 Q And you also filed a patent application?

19 A Yes.

20 Q And is it my understanding -- is my  
21 understanding correct that it is you and Dr. Elledge  
22 that created the Univector System?

23 A Yes.

24 Q Now, I understand that Ms. Li was involved in  
25 a -- I don't know how best to describe it -- a variation

## Page 9

1 of the Univector System where it was directed to  
 2 homologous recombination. Is that your understanding?  
 3 A It's all part of UPS system.  
 4 Q Okay. And is that part of what was in your  
 5 patent?  
 6 A I don't know.  
 7 Q Okay. Now, you collect royalties based on your  
 8 contribution, correct?  
 9 A Yes.  
 10 Q And do you -- what frequency do you receive  
 11 checks on that?  
 12 A I don't remember.  
 13 Q Do you recall how much you've received in  
 14 total, approximately?  
 15 A I can only estimate, but I'm not going to.  
 16 Q Was it \$100,000?  
 17 A Less than that.  
 18 Q Was it \$50,000?  
 19 A It's a couple of thousand dollars, I would say.  
 20 Q Just like \$2,000?  
 21 MS. MULLER: Objection; form.  
 22 A I will say a couple of thousand dollars.  
 23 Q (By Mr. Labgold) Okay. Well, I'm trying to get  
 24 an idea of what you mean by "a couple."  
 25 Colloquially in English, "a couple" would

## Page 10

1 be two?  
 2 A Oh, really?  
 3 Q Some people would say "a few" is three, but we  
 4 might differ on that.  
 5 A Approximately \$5,000.  
 6 Q And that's the total which you have received to  
 7 the best of your understanding?  
 8 A Per year.  
 9 Q Per year. Okay.  
 10 Were you involved in the decision of how  
 11 the royalties would be distributed amongst you and your  
 12 coinventors?  
 13 A No.  
 14 Q Let me mark as Lui Exhibit 1 a copy of a BCMT  
 15 document bearing production number BCM 001659 through  
 16 1664.  
 17 (Exhibit No. 1 marked.)  
 18 Q (By Mr. Labgold) If you take a look down at the  
 19 document about halfway through the page, there's a  
 20 heading there that says "Inventors."  
 21 A Uh-huh.  
 22 Q And then it gives a breakdown between you --  
 23 Ms. Li and yourself.  
 24 A Uh-huh.  
 25 Q And does this comport with your recollection

## Page 11

1 that for 1999 you received approximately \$5,000?  
 2 A You mean under the inventors, this part?  
 3 Q Yeah.  
 4 A Are you saying if the number looks correct?  
 5 Q Yeah, your general recollection?  
 6 A Yes.  
 7 Q Now, do you know why Ms. Li is not named as an  
 8 inventor on the patent?  
 9 A I don't know.  
 10 MS. MULLER: Objection; form.  
 11 Q (By Mr. Labgold) Was it your understanding that  
 12 your contribution to the development of the Univector  
 13 System and Ms. Li's were equivalent?  
 14 MS. MULLER: Objection; form.  
 15 A Can you rephrase the question?  
 16 Q (By Mr. Labgold) Do you believe that Ms. Li  
 17 contributed the same amount as you did to the  
 18 development of the Univector System?  
 19 MS. MULLER: Objection; form.  
 20 A No.  
 21 Q (By Mr. Labgold) Do you know why, then, Ms. Li  
 22 obtains the same royalties as you do?  
 23 A I don't know.  
 24 Q Have you ever discussed that with Dr. Elledge?  
 25 A No.

## Page 12

1 Q Have you ever discussed that with anybody else  
 2 at Baylor or BCMT?  
 3 A Yes.  
 4 THE WITNESS: Is that a privilege?  
 5 MS. MULLER: To the extent that you spoke  
 6 with counsel or involved communication of counsel, then  
 7 I instruct you not to answer.  
 8 A That involves discussion with patent counsel at  
 9 Baylor.  
 10 Q (By Mr. Labgold) Well, at any time did you  
 11 raise a concern with anyone at BCMT as to whether the  
 12 distribution of royalties was equitable?  
 13 MS. MULLER: Again, to the extent that  
 14 that requires you to discuss -- to disclose any  
 15 conversation with counsel, I instruct you not to answer.  
 16 MR. LABGOLD: And Counsel, I would -- I  
 17 don't have the energy or the time to deal with this. I  
 18 will just note on the record -- and I can tell we're  
 19 coming back for another deposition, and it's going to be  
 20 on your client's dime.  
 21 Because if he's going to Baylor and he's  
 22 complaining or inquiring as to why his amount is  
 23 equivalent to somebody who joined the project after the  
 24 patent was filed, that's not seeking legal counsel.  
 25 That's a business dispute.

## Page 13

1 Now, you can instruct him as you will.  
 2 I'll give you a moment to think about it. If you're  
 3 going to tell me the instruction stands, I'll move on,  
 4 and we'll deal with that later.  
 5 MS. MULLER: For the moment the  
 6 instruction stands.  
 7 MR. LABGOLD: Okay.  
 8 Q (By Mr. Labgold) Did you ever get an answer as  
 9 to why Ms. Li gets the same amount of royalties as you  
 10 do despite --  
 11 A No.  
 12 Q -- the fact that --  
 13 Fair enough.  
 14 I'd like to mark as Liu Exhibit 2 a copy  
 15 of an affidavit which you signed.  
 16 (Exhibit No. 2 marked.)  
 17 Q (By Mr. Labgold) Can you tell me if you've seen  
 18 this document before today?  
 19 A Yes.  
 20 Q Did you yourself prepare the text of the  
 21 document?  
 22 A Yes.  
 23 Q Did you type it yourself?  
 24 A No.  
 25 Q So if I understand correctly, you wrote the

## Page 14

1 text of the document and then forwarded it to somebody  
 2 else for typing?  
 3 MS. MULLER: Objection; privileged.  
 4 To the extent that that requires you to  
 5 reveal any conversation you had with counsel, again --  
 6 MR. LABGOLD: There is nothing privileged  
 7 about that. I am entitled to know how he prepared his  
 8 declaration, affidavit, whatever you want to call it,  
 9 his sworn statement.  
 10 Q (By Mr. Labgold) Are you going to --  
 11 MS. MULLER: If it involved a conversation  
 12 with counsel, I'm going to instruct him not to answer.  
 13 MR. LABGOLD: Have you done this before?  
 14 MS. MULLER: Sir?  
 15 MR. LABGOLD: Have you done this before?  
 16 MS. MULLER: I'm not being deposed here.  
 17 Q (By Mr. Labgold) When you signed this  
 18 affidavit, did you understand that you were under oath?  
 19 A Yes.  
 20 Q Did you understand what the consequences were  
 21 if you made a statement which were not true, to your  
 22 knowledge, in a sworn statement?  
 23 A Yes.  
 24 Q And do you understand that you are under oath  
 25 here today, and that if you do not tell the truth, that

## Pag 15

1 the penalty of perjury adheres to that?  
 2 A Yes.  
 3 Q Okay. If you take a look at Paragraph 2 under  
 4 Roman numeral two, says: (Reading) I contributed to the  
 5 development of the univector plasmid-fusion system.  
 6 What was your contribution?  
 7 A My contributions to develop the Cre enzyme and  
 8 show this concept, this system works in principle.  
 9 Q When you say "develop the Cre enzyme," what are  
 10 you talking about?  
 11 A Making the GST-Cre.  
 12 Q So making a GST-Cre fusion, correct?  
 13 A No.  
 14 Q Please explain.  
 15 A Not only that, more than that.  
 16 Q Okay. Please explain.  
 17 A Making the --  
 18 MS. MULLER: Objection; form. I'm sorry.  
 19 Go ahead.  
 20 A Making a fusion protein, express it, an E.  
 21 coli, purify it, demonstrate the purified protein has  
 22 high -- high specific activity.  
 23 Q (By Mr. Labgold) Okay. Now, GST fusion  
 24 proteins were known in the art prior to your work,  
 25 correct?

## Page 16

1 A Correct.  
 2 Q And the Cre enzyme itself was known in the art  
 3 prior to your work, correct?  
 4 A Correct.  
 5 Q And am I correct in understanding that the Cre  
 6 recombinases, the Cre enzyme, its ability to recombine  
 7 loxP site was also known in the art, correct?  
 8 A Correct.  
 9 Q If you take a look at page -- I'm sorry, we got  
 10 a stapling error here.  
 11 Actually, looking at Page 2 of your  
 12 declaration, and you say that the Univector System was  
 13 described and explained in an article and then it sets  
 14 forth the article. Do you see that?  
 15 A Uh-huh, the first two sentences.  
 16 Q Yes. And I'd like to mark -- let me give you a  
 17 document we've already marked as Elledge Exhibit 3, if  
 18 you can confirm for me that is the article to which you  
 19 were referring?  
 20 A Yes.  
 21 Q And when you prepared -- let me ask this: Were  
 22 you involved in the preparation of the article?  
 23 A Yes.  
 24 Q And to the best of your ability, did you  
 25 completely and fully describe the Univector System in

Page 17

1 the article?  
 2 A Yes.  
 3 Q And if I understand correctly, the goal of  
 4 preparing an article that goes into a peer reviewed and  
 5 public journal is to disseminate your research  
 6 information into the public, correct?  
 7 A Yes.  
 8 Q And the goal being that from your research  
 9 article, like the research articles which you cite in  
 10 your own paper, other people could take your information  
 11 and use it within the scientific community?  
 12 A Yes.  
 13 Q So am I correct in understanding that the  
 14 purpose of publishing your information is to publicly  
 15 disseminate the research information contained in the  
 16 article?  
 17 A Yes.  
 18 Q Now, in the paragraph of your declaration which  
 19 we were referring to, it also refers to a patent which  
 20 you've called the Univector System Patent. Do you see  
 21 that?  
 22 A Yes.  
 23 Q And I'd like to mark as Liu Exhibit 3 a copy of  
 24 U.S. Patent No. 5851808.  
 25 MR. LABGOLD: And I'll apologize to

Page 19

1 MS. MULLER: Objection --  
 2 Q (By Mr. Labgold) -- to the United States Patent  
 3 and Trademark Office.  
 4 MS. MULLER: -- to the extent that that  
 5 requires you to reveal communications between yourself  
 6 and counsel, I instruct you not to answer that.  
 7 Q (By Mr. Labgold) Did you have an understanding  
 8 that you had an obligation, an uncompromising duty of  
 9 candor?  
 10 MS. MULLER: Again, to the extent that  
 11 that -- that you would have to reveal conversations  
 12 between yourself and counsel, I instruct you not to  
 13 answer that.  
 14 Q (By Mr. Labgold) Did you have an understanding  
 15 that you had to disclose what is known as the best mode  
 16 of practicing your invention at the time your  
 17 application is filed?  
 18 MS. MULLER: Same objection.  
 19 Q (By Mr. Labgold) Are you going to follow your  
 20 counsel's instruction on -- every time she tells you not  
 21 to answer?  
 22 A Yes.  
 23 Q Okay. That just saves me a little trouble and  
 24 saves the court a little trouble later when I have to go  
 25 through the record.

Page 18

1 Counsel, I only have one copy.  
 2 MS. MULLER: That's okay.  
 3 MR. LABGOLD: Off the record.  
 4 (Exhibit No. 3 marked)  
 5 (Discussion off the record.)  
 6 Q (By Mr. Labgold) Can you confirm for me that  
 7 that is the patent to which you were referring, on Page  
 8 2 of Liu Exhibit 2?  
 9 A Yes.  
 10 Q And this is the patent to which you previously  
 11 referred to which you and Dr. Elledge were inventors,  
 12 correct?  
 13 A Correct.  
 14 Q And I don't know if this will refresh your  
 15 recollection, if you note that there's a filing date  
 16 here indicating that the patent application was filed on  
 17 February 28th, 1997, do you recall that Ms. Li joined  
 18 the lab in approximately March of 1997?  
 19 A I don't recall.  
 20 Q Okay. Now, was this the first patent  
 21 application you had ever filed?  
 22 A Yes.  
 23 Q And when you were preparing your patent  
 24 application, were you advised that you had an obligation  
 25 to disclose all relevant prior art information --

Page 20

1 Did you comply with your duty of candor  
 2 obligations as imposed by 37 CFR 1.56A?  
 3 MS. MULLER: Objection; form.  
 4 A What's C --  
 5 Q (By Mr. Labgold) Has anybody ever told you  
 6 about the duty of candor which is owed to the Patent  
 7 Office?  
 8 MS. MULLER: To the extent that that would  
 9 require you to reveal conversations with counsel, I  
 10 instruct you not to answer.  
 11 Q (By Mr. Labgold) Have you ever been told that  
 12 it's necessary during the prosecuting of your patent  
 13 application to reveal all relevant material information  
 14 to the United States Patent and Trademark Office?  
 15 MS. MULLER: Same instruction.  
 16 Q (By Mr. Labgold) And again, you're not going to  
 17 answer the question, correct?  
 18 A Yes.  
 19 Q Did you identify to the United States Patent  
 20 and Trademark Office all relevant and material  
 21 information that you are aware of at the time of the  
 22 filing of your patent application?  
 23 MS. MULLER: Same instruction.  
 24 MR. LABGOLD: Not to answer?  
 25 MS. MULLER: To the extent that it would

NO. 2001-61352

BAYLOR COLLEGE OF MEDICINE  
and BCM TECHNOLOGIES, INC.

VS.

CLONTECH LABORATORIES, INC.

VS.

INVITROGEN CORPORATION

\* IN THE DISTRICT COURT OF  
\*

\* HARRIS COUNTY, T E X A S  
\*

\*

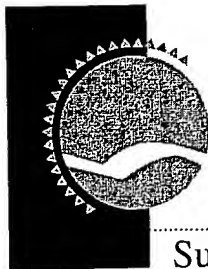
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\* 133RD JUDICIAL DISTRICT

\*\*\*\*\*

THE ORAL  
DEPOSITION OF  
MAMIE LI  
FEBRUARY 6, 2003

\*\*\*\*\*



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JOB NO. 39663

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## ORAL DEPOSITION OF MAMIE LI

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WITNESS: MAMIE LI

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\* \* \* \* \*



ORAL DEPOSITION OF MAMIE LI

1           ORAL DEPOSITION OF MAMIE LI, produced as a witness  
2 at the instance of the DEFENDANT/COUNTERCLAIM PLAINTIFF  
3 and duly sworn, was taken in the above-styled and  
4 numbered cause on the 6th of February, 2003, from  
5 1:08 p.m. to 3:27 p.m., before Debbie K. Forrester, CSR,  
6 in and for the State of Texas, reported at the offices  
7 of Vinson & Elkins, L.L.P., 1001 Fannin, 37th Floor,  
8 Houston, Texas, pursuant to the Texas Rules of Civil  
9 Procedure and the provisions stated in the record or  
10 attached hereto.

11

A P P E A R A N C E S

12

13

14 FOR THE PLAINTIFF/COUNTERCLAIM DEFENDANT BAYLOR COLLEGE  
OF MEDICINE and BCM TECHNOLOGIES, INC., and ADDITIONAL  
15 COUNTERCLAIM DEFENDANT INVITROGEN CORPORATION:

15

16

17

18

19

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24

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Mr. David P. Blanke  
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Mr. Marc Labgold  
Patton Boggs, L.L.P.  
2550 M Street, NW  
Washington, DC 20037-1350

\* \* \* \* \*

## ORAL DEPOSITION OF MAMIE LI

1 we mutated it, the strain itself is --

2 Q (BY MR. LABGOLD) Right. What I'm saying is,  
3 for example, do you know e. coli K12?

4 A Uh-huh.

5 Q And so if you started from e. coli K12 and you  
6 disabled the recA gene, then we would put down "K12" and  
7 then paren "recA minus" or "recA1"; correct?

8 A Correct.

9 Q And so the purpose of setting forth the  
10 genotype in this fashion is to let the skilled  
11 individual understand this is the mutation which has  
12 occurred and it provides the proper function?

13 A Correct.

14 Q Now, if you look at Figure 1, what does this  
15 show?

16 A It shows a scheme of Cre-lox reaction.

17 Q Now, is it your understanding that Dr. Elledge  
18 invented the Cre-lox recombination, in general?

19 A Yes.

20 Q Let me back up. Aside from what is set forth  
21 in the figure, the recognition that you could use, for  
22 example, lox p sites with cre recombinase, that was  
23 something that was known prior to Dr. Elledge's  
24 development of this system; correct?

25 A Correct.

## ORAL DEPOSITION OF MAMIE LI

1 Q And the concept of using the lox p sites with a  
2 cre recombinase was known in the prior art; correct?

3 A Can you repeat the question?

4 MR. LABGOLD: Would you read it back?

5 THE REPORTER: "And the concept of using  
6 the lox p sites with a cre recombinase was known in the  
7 prior art; correct?"

8 A Yes.

9 Q (BY MR. LABGOLD) And would it be fair to say  
10 that -- let me back up.

11 Plasmids were clearly known in the prior  
12 art, prior to the development of the Univector system;  
13 correct? Just the concept of a plasmid was known before  
14 Dr. Elledge developed the --

15 A Correct.

16 Q And a kanamycin resistance gene was known in  
17 the art prior to Dr. Elledge's invention; correct?

18 A Correct.

19 Q And the ampicillin resistance gene was known in  
20 the art prior to Dr. Elledge's invention?

21 A Correct.

22 Q And the use of either the kanamycin or the  
23 ampicillin or a host of other antibiotic resistance  
24 genes applied to a plasmid was known in the art prior to  
25 Dr. Elledge's development of the Univector system;

## ORAL DEPOSITION OF MAMIE LI

1 correct?

2 MR. BLANKE: I'm sorry. I lost that for a  
3 second. Can I get that read back, please?

4 THE REPORTER: "And the use of either the  
5 kanamycin or the ampicillin or a host of other  
6 antibiotic resistance genes applied to a plasmid was  
7 known in the art prior to Dr. Elledge's development of  
8 the Univector system; correct?"

9 A I'm a little confused. Using the kanamycin and  
10 ampicillin together in a --

11 Q (BY MR. LABGOLD) What I'm saying is plasmids  
12 containing antibiotic resistance genes were known in the  
13 art prior to Dr. Elledge's development of the Univector  
14 system; correct?

15 A Correct.

16 Q And, in fact, many of the antibiotic resistance  
17 genes have been isolated from bacteria, from plasmids  
18 which are transferred from bacteria to bacteria;  
19 correct?

20 A Correct.

21 Q And, finally, the GST-Cre fusion protein was  
22 known in the art prior to Dr. Elledge's development of  
23 the Univector system; correct?

24 A That, I don't know.

25 Q Is it -- if you take a look at your paper, in

## ORAL DEPOSITION OF MAMIE LI

1 the second column and it says "For a routine analysis of  
2 a new gene, it might be desirable to express it in  
3 bacteria as a glutathione-S-transferase fusion protein  
4 or with a six histidine (His6) tag for purification and  
5 antibody production." Do you see that?

6 A Uh-huh.

7 Q Does that refresh your recollection that the  
8 GST fusion proteins were known in the art prior to  
9 Dr. Elledge's development of the Univector system?

10 A For GST fusion proteins, yes.

11 Q And so is it fair to say that the -- is it fair  
12 to say that what Dr. Elledge achieved was to take these  
13 elements and to use them in a way which would achieve  
14 this facile recombination process?

15 A Can you repeat the question?

16 MR. LABGOLD: Let's have it read back.

17 THE REPORTER: "And so is it fair to say  
18 that the -- is it fair to say that what Dr. Elledge  
19 achieved was to take these elements and to use them in a  
20 way which would achieve this facile recombination  
21 process?"

22 A What's "facile" mean?

23 Q Rapid, easy.

24 So, basically, what I'm saying: Would it  
25 be fair to say that he took these known elements and

## ORAL DEPOSITION OF MAMIE LI

1 combined them in a way which achieved this result of the  
2 Univector system?

3 A Not everybody can do that.

4 Q Oh, I'm not saying that they can.

5 A That is true. These elements are all known,  
6 but I don't think not everybody can think of a way to  
7 put -- to use Cre-lox to put two plasmids together  
8 making fusions in a rapid way.

9 Q So if I understand correctly, the novelty, to  
10 the extent that any exists, relates to the combination  
11 and how they're combined as opposed to the individual  
12 components?

13 A Yes. To me, it's the concept of putting these  
14 things together.

15 Q Now, is this Figure 1 -- is this an accurate  
16 representation -- I'm sorry. I'm in the document that  
17 you sent out with the kit.

18 A Oh, okay.

19 Q This is on the page bearing the Production  
20 No. 370. Does this picture fairly depict how the  
21 recombination occurs?

22 A Yes.

23 Q And although in simple diagram form, does this  
24 convey to people of skill the recombination which occurs  
25 between the two plasmids?

## ORAL DEPOSITION OF MAMIE LI

1 Q Now, I notice that there's two bacterial  
2 strains here, both of which are Barry Wanner strains?

3 A That's right.

4 Q And do you have a recollection that one of the  
5 features of some of these strains is that they have a  
6 conditional origin of replication?

7 A That's right.

8 Q And the conditional origin of replication was  
9 not developed by Dr. Elledge; correct?

10 A No.

11 Q This list does not include one of the strains  
12 which is shown here in the bacterial strain table on the  
13 page ending in 369, BUN10. Do you see that?

14 A Yes, I see that.

15 Q Do you know what that strain is useful for?

16 A That strain is mainly used for homologous  
17 recombination.

18 Q So if you're not using homologous  
19 recombination, you wouldn't use the BUN strains;  
20 correct?

21 A You can use that to replicate pUNI.

22 Q But not for carrying out the homologous  
23 recombination?

24 A You can use it for both. You can replicate  
25 pUNI in that strain also.

## ORAL DEPOSITION OF MAMIE LI

1       A       Correct.

2       Q       And prior to the development of the Univector  
3 system, were there strains that were known to be useful  
4 with plasmids having conditional origins of replication?

5       A       I don't know that. I don't know much about --  
6 I don't know that much detail about bacteria before  
7 then.

8       Q       But you did testify the conditional origenes of  
9 replication were known; correct?

10      A       That's correct.

11      Q       So, again, if you don't know, that's fine, but  
12 doesn't that lead you to the conclusion that if the  
13 conditional ori plasmids were in existence there must  
14 have been strains that could propagate them?

15      A       That's right.

16      Q       Now, if I understand the process correctly,  
17 then, you got an e-mail from Dr. Elledge. He told you  
18 what to send. You would then prepare the package and  
19 send that out to Dr. Archdeacon, or whoever the  
20 individual is, along with the paper materials?

21      A       That's right?

22                   MR. BLANKE: Could I get that read back?

23                   THE REPORTER: "Now, if I understand the  
24 process correctly, then, you got an e-mail from  
25 Dr. Elledge. He told you what to send. You would then



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CAUSE NO. 2001-61352

BAYLOR COLLEGE OF MEDICINE) IN THE DISTRICT COURT

and BCM TECHNOLOGIES, INC.)

)

Plaintiffs, )

VS. ) HARRIS COUNTY, TEXAS

)

CLONTECH LABORATORIES, )

INC., )

)

Defendants. ) 133RD JUDICIAL DISTRICT

\*\*\*\*\*

ORAL DEPOSITION OF

STEPHEN J. ELLEDGE

JULY 17, 2002

\*\*\*\*\*

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THE ORAL DEPOSITION OF STEPHEN J.

ELLEDGE, produced as a witness at the instance of the Defendants, and duly sworn, was taken in the above-styled and numbered cause on the 17th day of July, 2002, from 10:00 a.m. to 2:50 p.m., before R. Patrick Tate, CSR in and for the State of Texas, reported by machine shorthand, at the offices of Baylor Colledge of Medicine, 1200 Cullen, Houston, Harris County, Texas pursuant to the Texas Rules of Civil Procedure.

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1 FOR THE PLAINTIFF:

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3 Patrick Turley, Esq.

4 Associate General Counsel

5 Baylor College of Medicine

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7 Houston, Texas 77030

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9 FOR DEFENDANT CLONTECH:

10 Marc R. Labgold, Esq.

11 Richard J. Oparil, Esq.

12 Patton Boggs, L.L.P.

13 2550 M Street, N.W.

14 Washington, D. C. 20037

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EXAMINATION INDEX

Examination by Mr. Labgold..... 4

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1 E. coli.

2 Q. Now, if we keep that picture open and you  
3 turn to your article, which is the document we've  
4 marked as Exhibit 3, I'd like to go to figure 1 of  
5 that document which is on page 1302 of the article,  
6 146 production number, is what you've just  
7 described the same as what's described at the top  
8 of -- top right-hand -- top left-hand corner of  
9 figure 1 of the paper?

10 A. It's similar in essence, yes. I mean,  
11 the -- sort of the general idea is conveyed. This  
12 is similar in both of those. There's a little more  
13 detail on the paper.

14 Q. But the same concept, if you will, of how  
15 it works?

16 A. Yes.

17 Q. Okay. Now, with regard to the lox sites,  
18 did you discover the lox sites or were they  
19 described in prior references?

20 A. The loxP site had been previously  
21 published, and I created the loxH site and a few  
22 other variants that don't have names.

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1 Q. And the cre mediation for the loxP  
2 recombination, had that been previously described  
3 in the prior art?

4 A. Yes.

5 Q. Now, I believe if I understand correctly,  
6 your, the rapidity of the screening method relies  
7 in part upon the conditional origin of replication,  
8 correct?

9 A. When you say the screening method, what  
10 exactly do you mean?

11 Q. Well, explain how the conditional origin  
12 of replication, what its function is?

13 A. Oh, its function is to prevent the  
14 Univector or recombination, certain recombination  
15 products that include the Univector, it precludes  
16 them from replicating by themselves in the host E.  
17 coli strain that you transformed them into.

18 Q. So that for the nontechnically inclined,  
19 after you've done the recombination, in order to be  
20 able to isolate the species out of all the possibly  
21 species which are generatable, the conditional  
22 origin of replication will help remove the

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1 background of the pUNI vector, itself, correct?

2 A. Yes, actually in many respects it's very  
3 similar to the Clontech --

4 Q. Does the Clontech --

5 A. -- Creator system. They have a  
6 conditional origin also.

7 Q. We'll get to that in a moment. And the  
8 kanamycin resistance, the function of that is also  
9 a screening; is that correct?

10 A. Yes. You need a drug in this embodiment  
11 to make sure that your -- the linked sequence,  
12 which is the gene, is transferred.

13 Q. And the two that you have embodied in  
14 your examples are kanamycin and ampicillin  
15 resistance, correct?

16 A. Yes.

17 Q. And those were genes that you did not  
18 discover, correct?

19 A. That's correct.

20 Q. Had you discovered the conditional origin  
21 of replication?

22 A. No, it was previously published.

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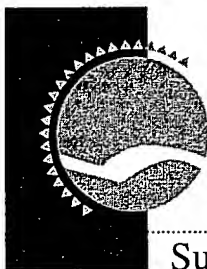
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and BCM TECHNOLOGIES, INC. (  
(  
Vs. ( HARRIS COUNTY, T E X A S  
CLONTECH LABORATORIES, INC. (  
(  
VS. (   
(  
INVITROGEN CORPORATION ( 133RD JUDICIAL DISTRICT

\*\*\*\*\*

ORAL DEPOSITION OF  
STEPHEN ELLEDGE, Ph.D.  
MARCH 26, 2003

\*\*\*\*\*

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## ORAL DEPOSITION OF STEPHEN ELLEDGE, Ph.D.

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Number	Description	Page Marked
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31	E-mail string with production Numbers BCM 003154-55	43

\* \* \* \* \*

## ORAL DEPOSITION OF STEPHEN ELLEDGE, Ph.D.

1 ORAL DEPOSITION OF STEPHEN ELLEDGE Ph.D., produced as  
2 a witness at the instance of the DEFENDANT/COUNTERCLAIM  
3 PLAINTIFF, and duly sworn, was taken in the above-styled  
4 and numbered cause on MARCH 26, 2003, from 9:04 a.m. to  
5 11:20 a.m., before Linda Rayburn, CSR in and for the  
6 State of Texas, reported at Baylor College of Medicine,  
7 1 Baylor Plaza, Cullen Building, Suite 106-A, Houston,  
8 Texas, pursuant to the Texas Rules of Civil Procedure  
9 and the provisions stated in the record or attached  
10 hereto.

## A P P E A R A N C E S

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18 -AND-

19 MR. PATRICK TURLEY  
20 Baylor College of Medicine  
General Counsel Office  
21 1 Baylor Plaza  
Houston, Texas 77002

22  
23 FOR THE DEFENDANTS/COUNTERCLAIM PLAINTIFF:

24 MR. MARC R. LABGOLD  
25 Patton Boggs, LLP  
8484 Westpark Drive, Suite 900

## ORAL DEPOSITION OF STEPHEN ELLEDGE, Ph.D.

1 of the Univector system.

2 Q And in fact, all of the elements of the  
3 Univector system, and take it in unconnected form, were  
4 all known in the prior art, correct?

5 A It depends on what you mean by "elements." I  
6 don't know what you mean, so perhaps you could define  
7 that for me, because it's a very vague term.

8 Q Why don't you tell me what makes up the  
9 Univector system.

10 MR. BLANKE: Objection, form.

11 Q (By Mr. Labgold) Or why don't you -- I'll make  
12 it a little more defined. What do you consider to be  
13 the essential elements of the Univector system?

14 MR. BLANKE: Objection, form.

15 THE WITNESS: I consider the essential  
16 elements of the Univector system to be the ability to  
17 cause the fusion between two molecules using  
18 site-specific recombination, one of those molecules  
19 being a recipient vector, the other being a donor vector  
20 that contains site-specific recombination site, a drug  
21 marker and the absence of a functional origin under  
22 certain conditions --

23 Q And --

24 A The ability to select for that event.

25 Q Now, the prior art taught site-specific

## ORAL DEPOSITION OF STEPHEN ELLEDGE, Ph.D.

1 recombination, correct?

2 A That is correct.

3 Q And the prior art taught the use of lox sites  
4 for site-specific recombination, correct?

5 A That is correct.

6 Q And the prior art taught Cre-mediated  
7 recombination using the lox sites?

8 A That is correct.

9 Q And the prior art taught drug resistance  
10 markers, right?

11 A Correct.

12 Q And the prior art taught conditional origins of  
13 replication, correct?

14 A Correct.

15 Q And the prior art, one that you didn't mention  
16 here, but I think is also important to the system,  
17 correct me if I'm wrong, the prior art taught cells  
18 which would allow for the selection of the conditional  
19 origin of replication, correct?

20 A That is correct.

21 Q So --

22 A And also, I would add, I don't know, "element"  
23 is a -- I mean, there is also the concept of the purpose  
24 of making the fusion event to create expression vectors  
25 and things like that. That was a novel element.

## ORAL DEPOSITION OF STEPHEN ELLEDGE, Ph.D.

1           Q     Well, expression vectors were known before,  
2 correct?

3           A     Right. But I think the use of site-specific  
4 recombination in this way wasn't appreciated, so that  
5 that I think is a novel element, because without the  
6 need to do that, there would be no coming together of  
7 the other elements.

8           Q     But prior to your invention, people clearly  
9 desired and actually accomplished the ability to  
10 subclone pieces of DNA from one vector to another,  
11 correct?

12          A     Yes, using conventional methods.

13          Q     And some of those conventional methods would be  
14 what I would refer to as kind of traditional subcloning  
15 where you excise a DNA sequence of interest from one  
16 plasmid using restriction enzymes and put them into  
17 another plasmid having complementary restriction sites,  
18 correct?

19          A     That's correct.

20          Q     And in certain circumstances, the first vector  
21 would be what might be called a cloning vector which was  
22 unable to express the gene of interest, correct?

23          A     Yes, that's one example.

24          Q     And one of the purposes for wanting to subclone  
25 this gene of interest from that cloning vector is to put

## ORAL DEPOSITION OF STEPHEN ELLEDGE, Ph.D.

1 it into what we call an expression vector so that the  
2 gene of interest would be juxtaposed in proper reading  
3 frame with a promoter, correct?

4 A That is correct.

5 Q And therefore that would allow for the  
6 expression in the host cell under the right conditions  
7 of the gene of interest, correct?

8 A Yes.

9 Q And so is it fair to say that the -- do you  
10 understand the word "novelty" as it --

11 A I have an understanding of it, yes.

12 Q Okay. Well, for the sake of getting past the  
13 point, would it be fair to say that the novelty of your  
14 system was not that it had new elements, but that these  
15 elements were arranged in a way that had not been  
16 previously arranged to achieve the result which you  
17 achieved?

18 A Yes.

19 Q Now, you filed a patent application on which  
20 you consider to be your invention, correct?

21 A That is correct.

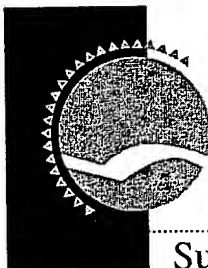
22 MR. LABGOLD: And I apologize. I did not,  
23 as I was handing out all those extra copies, one of the  
24 reasons was I was supposed to have an extra copy for  
25 today. Do you have yesterday's exhibits?

CAUSE NO. 2001-61352

BAYLOR COLLEGE OF MEDICINE ( IN THE DISTRICT COURT OF  
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(  
Vs. ( HARRIS COUNTY, T E X A S  
CLONTECH LABORATORIES, INC. (  
(  
VS. (   
(  
INVITROGEN CORPORATION ( 133RD JUDICIAL DISTRICT

\*\*\*\*\*  
ORAL DEPOSITION OF  
KENNETH N. KREUZER, Ph.D.  
MARCH 25, 2003  
\*\*\*\*\*

**EXHIBITS  
BOUND  
SEPARATELY**



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## ORAL DEPOSITION OF KENNETH N. KREUZER, Ph.D.

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## ORAL DEPOSITION OF KENNETH N. KREUZER, Ph.D.

1 ORAL DEPOSITION OF KENNETH N. KREUZER, Ph.D.,  
2 produced as a witness at the instance of the  
3 DEFENDANT/COUNTERCLAIM PLAINTIFF, and duly sworn, was  
4 taken in the above-styled and numbered cause on MARCH  
5 25, 2003, from 10:00 a.m. to 2:22 p.m., before Linda  
6 Rayburn, CSR in and for the State of Texas, reported at  
7 the offices of Vinson & Elkins, 1001 Fannin Street,  
8 Suite 2300, Houston, Texas, pursuant to the Texas Rules  
9 of Civil Procedure and the provisions stated in the  
10 record or attached hereto.

11

12

## A P P E A R A N C E S

13

14 FOR THE PLAINTIFF/COUNTERCLAIM DEFENDANT:

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27

28

\* \* \* \* \*

29

## ORAL DEPOSITION OF KENNETH N. KREUZER, Ph.D.

1 to "donor vector," which we see down a little further on  
2 the page?

3 A Sure.

4 Q And one last question and we'll take our break.  
5 Your definition of "donor vector," is that concept there  
6 something which was invented by Dr. Stephen Elledge?

7 A I think it would be the same answer as before.

8 MR. LABGOLD: Why don't we go ahead and  
9 take a quick break.

10 (A recess was taken.)

11 Q (By Mr. Labgold) Back to our Glossary of  
12 Terms, I assume you will agree with me that Dr. Elledge  
13 did not invent the concept of antibiotics?

14 A Certainly.

15 Q And you also agree that he did not invent the  
16 idea of using antibiotic resistant genes as selection  
17 markers?

18 A Yes.

19 Q Conditional origin of replication, is that a  
20 concept which was invented by Dr. Elledge?

21 A No.

22 Q Do you know if it was published in the art  
23 before the development of the Univector system?

24 A Sure.

25 Q And do you know if its use in cloning

## ORAL DEPOSITION OF KENNETH N. KREUZER, Ph.D.

1 technologies was discussed in the literature prior to  
2 the Elledge Univector development?

3 A Yes.

4 Q Are you aware -- pardon me?

5 A It's used in a variety of situations.

6 Q Are you aware that Dr. Elledge received certain  
7 bacterial strains from a Dr. Barry Wanner at Purdue?

8 A Yes.

9 Q And are you aware of the fact that Dr. Elledge  
10 provided those strains to Clontech without advising  
11 Dr. Wanner of that fact beforehand?

12 MR. BLANKE: Objection, form.

13 THE WITNESS: I don't know what the  
14 communication was between Dr. Elledge and Dr. Wanner.

15 Q (By Mr. Labgold) Have you seen that allegation  
16 in the record?

17 A The allegation that it was provided without  
18 proper communication?

19 Q Yes.

20 A I think I have, yes.

21 Q Have you seen -- I believe in your report you  
22 indicated that you've seen all of the documents that  
23 have been produced by both parties; is that correct?

24 A As far as I know. I came to Austin and was  
25 presented with what was thirteen or fifteen boxes of

## ORAL DEPOSITION OF KENNETH N. KREUZER, Ph.D.

1 with licensing.

2 Q That there was a third-party that had certain  
3 rights to the GST fusion purification system? That's  
4 what the concern was?

5 A That's my recollection.

6 Q And from your review of the documents, Clontech  
7 was cognizant of the fact that they did not want to use  
8 someone else's technology?

9 A Hang on a minute. I could be wrong, but that's  
10 my recollection at the moment.

11 Q And Dr. Elledge did not invent GST fusion  
12 proteins, correct?

13 A No.

14 Q That's correct or not correct?

15 A Oh, sorry. Dr. Elledge did not invent GST  
16 fusion proteins as a general entity, yes.

17 Q And he did not invent the concept of creating a  
18 GST fusion so that the protein to which the GST was  
19 fused could be purified, correct?

20 A That's correct.

21 Q And in fact, the publication, itself, makes  
22 reference to that and being in the prior art, correct?

23 A Yes.

24 Q Did you review the correspondence between  
25 Clontech and Dr. Elledge concern Clontech's efforts to

## ORAL DEPOSITION OF KENNETH N. KREUZER, Ph.D.

1 (Discussion off the record.)

2 Q (By Mr. Labgold) I would like to mark as  
3 Kreuzer Exhibit 3 a publication in Gene, the journal  
4 Gene, G-e-n-e, Volume 150, 1994, Pages 51 to 56,  
5 entitled, "Escherichia coli genome targeting, I.  
6 Cre-lox-mediated in vitro generation of ori minus  
7 plasmids and their in vivo chromosomal integration and  
8 retrieval."

9 (Kreuzer Deposition Exhibit No. 2 was  
10 marked for identification.)

11 MR. LABGOLD: Back on the record here. We  
12 have misidentified it. This article, Hasan, et al.,  
13 from Dr. Szybalski's lab will be Exhibit 2.

14 Q (By Mr. Labgold) If you'd take a moment to  
15 look at this article and tell me if you've seen this  
16 before?

17 A I believe I've seen a related paper. It may  
18 be -- maybe it's number two in the series. I'm not sure  
19 I've seen this one.

20 Q And do you understand this as being -- where it  
21 says Cre-lox-mediated, this is the same type of Cre-lox  
22 recombination that we're talking about, correct?

23 A That would be -- the reaction, itself, would be  
24 the same kind of reaction, yes.

25 Q And do you understand that this is a -- a

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1 method for inserting genes of interest into an acceptor  
2 molecule, in this case a chromosome?

3 A Again, I would need some time to read through  
4 the paper carefully, but it seems -- seems like that's  
5 what the title and abstract are, just guessing.

6 Q And to the extent you need to review any of it  
7 in detail, please take as much time as you need. Would  
8 you agree that the article describes putting a gene of  
9 interest onto a -- a plasmid -- well, let's take a look  
10 at Figure 1.

11 A Okay.

12 Q And why don't you take a moment to read the  
13 legend to Figure 1.

14 A Okay.

15 Q And do you have a general understanding of  
16 what's represented by this figure?

17 A Yes, I think so.

18 Q And is it your understanding that the top  
19 plasmid, the top circle there, pNH64a, is used to -- as  
20 a vector for a gene of interest?

21 A Yes.

22 Q And that that vector contains the two loxP  
23 sites?

24 A Yes.

25 Q Which when subjected to the Cre enzyme in vitro

## ORAL DEPOSITION OF KENNETH N. KREUZER, Ph.D.

1 results in a recombination event that yields two  
2 plasmids that are shown as pNH64b and pNH64c?

3 A Yes.

4 Q Now, what's your understanding of that ori  
5 minus notation?

6 A That's a circular fragment of DNA that will go  
7 on to insert into bacterial chromosome.

8 Q And by it being ori minus, that means that that  
9 plasmid cannot propagate in a host organism, correct?

10 A At least not a wild type host organism.

11 Q And that ori minus feature is used as a  
12 selection for the desired reaction, correct?

13 A Yes, it's used as a negative selection for the  
14 desired reaction. Not the reaction that's shown here.

15 Q Correct.

16 A The reaction that occurs later.

17 Q And if I understand what is intended to happen  
18 next is that the result of the in vitro recombination  
19 with Cre -- oh, and let me ask you this, backing up a  
20 step. You've described in your expert report that this  
21 Cre-mediated reaction is a reversible reaction, correct?

22 A Yes.

23 Q So that where it shows an arrow coming from the  
24 big plasmid on the top of Figure 1 of Kreuzer Exhibit 2,  
25 down to the two daughter plasmids, that's actually -- it

## ORAL DEPOSITION OF KENNETH N. KREUZER, Ph.D.

1 should be a two-way arrow, correct?

2 A Yes.

3 Q And that I believe -- and I apologize, because  
4 I don't know exactly where the citation is in your --  
5 oh, I believe if you go to Page 21, I'm sorry, you state  
6 that after the two -- do you see about halfway down  
7 Page 45?

8 A Yes.

9 Q "After the two have been mixed together in the  
10 presence of Cre, you will have a mixture of vectors.  
11 Because the Cre reaction is reversible, vectors will be  
12 fusing and separating in the test tube until you stop  
13 the reaction."

14 A Yes.

15 Q And so that type of reversible equilibrium is  
16 actually going on in this reaction, too, correct?

17 A Yes, I mean, as I indicated in the report,  
18 depending on the DNA concentration, you can push it one  
19 way or the other.

20 Q And what's not shown in Figure 1 of Kreuzer  
21 Exhibit 2 is that you then transform this into a host  
22 organism, correct?

23 A Correct.

24 Q And then the chromosome of that host organism  
25 works as an acceptor molecule, if you will, for



## ORAL DEPOSITION OF KENNETH N. KREUZER, Ph.D.

1       Q     And by that system, you have a selection  
2 mechanism so that you can select for a resulting  
3 organism that displays the gene of interest and you will  
4 know by the means of the selection that you've got the  
5 right mutagenized product, correct?

6       A     You would certainly want to confirm it, but you  
7 would -- if the system works properly, you would have  
8 that, yes. And again, I haven't looked past Figure 1,  
9 so I'm assuming the system works by the lambda  
10 recombination. Right. And that's clearly indicated in  
11 the abstract.

12       Q     Uh-huh. Now, if Dr. Elledge was aware of this  
13 paper before the development of the Univector system,  
14 would the ethic provide that he should cite this  
15 reference in his article?

16       A     I don't particularly see why at the moment. I  
17 don't think his system is built on this at all.

18       Q     Even though it uses several of the key elements  
19 here?

20       A     As you pointed out before, there were quite a  
21 number of papers that use lox-mediated recombination in  
22 a variety of situations.

23       Q     And this one actually goes through taking a  
24 gene of interest, putting it into a plasmid, creating a,  
25 you know, donor plasmid, if you will, in the ori minus?

## ORAL DEPOSITION OF KENNETH N. KREUZER, Ph.D.

1       A       The words "donor" and "acceptor" don't mean  
2 very much. The heart of the Elledge system, you know,  
3 as I indicated, is the ability to make novel gene  
4 combinations, gene fusions, promoter gene constructs.  
5 And, you know, other people, as I said before, have used  
6 lox sites, for example, to introduce mutations into  
7 mouse gene targeting. Those are interesting other  
8 applications of lox recombination, but I don't think  
9 that the Elledge system is built on any of those, you  
10 know, as far as I can see.

11       Q       Uh-huh. Would you agree that the insertion of  
12 the gene of interest, the recombination event in Kreuzer  
13 Exhibit 2 into the chromosome is also a reversible  
14 reaction?

15       A       I don't believe that it is in the cells that  
16 they use. Int is -- only refers to when another protein  
17 is present, and I doubt if they have that protein  
18 present in the cells. But I would have to look at the  
19 materials and methods to determine that.

20       Q       And what's the enzyme, the protein that you are  
21 referring to?

22       A       XIS, X-I-S. I would -- again, I would have to  
23 look over it carefully. The normal -- let me clarify.  
24 The normal lambda integration which uses -- in the case  
25 of the Int protein, the two sites are different, they

## ORAL DEPOSITION OF KENNETH N. KREUZER, Ph.D.

1 are not the same as with the Cre-lox system. And the  
2 normal reaction which occurs between the two different  
3 sites goes in one direction with Ints and requires an  
4 XIS for the reverse direction.

5 I would have to look over this more  
6 carefully to see. It looks to me like they are using  
7 the normal bacterial -- they are using the normal  
8 combination of two sites, and so my presumption, if that  
9 is true, is that it would require a second protein.

10 Q If you'd take a look at Page 55, Subsection D.

11 A Okay.

12 Q And take as much time as you need to read that  
13 section and just --

14 MR. BLANKE: We're on Exhibit 2 of the  
15 Kreuzer deposition?

16 MR. LABGOLD: Yes, sir. I'm sorry,  
17 Kreuzer Exhibit 2 at Page 55. And it's in bold,  
18 Subsection D on the left-hand column.

19 THE WITNESS: Okay. Yes.

20 Q (By Mr. Labgold) Doesn't this indicate that  
21 the inserted gene product can actually be retrieved from  
22 the chromosome?

23 A By introducing the excising protein.

24 Q Now, if you go to Page 22 of your report, which  
25 is Kreuzer Exhibit 1, at the top of the page, you have a

Michael H. Milby, Clerk

### **The Parties**

2. Plaintiff Clontech Laboratories, Inc. ("Clontech") is a corporation organized under the laws of the state of Delaware and having its principal place of business at 1020 East Meadow Circle, Palo Alto, California, 94303.

3. On information and belief, Defendant BCM Technologies, Inc. is a corporation organized under the laws of the state of Delaware and having its principal place of business at 1709 Dryden Road, Suite 900, Houston, Texas 77030 ("BCMT").

4. On information and belief, Defendant Baylor College of Medicine is a nonprofit corporation organized and existing under the laws of the State of Texas and having a principal place of business at One Baylor Plaza, Houston, Texas 77030 ("Baylor").

### **Venue and Personal Jurisdiction**

5. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b)-(c). Defendant Baylor, a Texas nonprofit corporation and Defendant BCMT, a corporation having its principal place of business in Houston, Texas, have accused Plaintiff of using its patented technology and threatened to sue Plaintiff, a Delaware corporation doing business in the State of Texas, for patent infringement. Venue for such a suit is proper in this district and in Texas given that both corporate Defendants reside therein.

### **The Patent-in-Suit**

6. On information and belief, Baylor is the assignee of United States Patent No. 5,851,808 to Stephen J. Elledge and Qinghua Liu, entitled RAPID SUBCLONING USING SITE-SPECIFIC RECOMBINATION, and which issued on December 22, 1998 (“the ’808 patent”). (A copy of the ’808 patent is appended hereto as Exhibit A).

### **Case or Controversy**

7. An immediate, real, and justiciable controversy exists between the parties to this action. As set forth in paragraphs 8-19 below, Baylor and BCMT have threatened Clontech in a manner which has caused Clontech to have a reasonable apprehension that the Defendants will sue Clontech for the alleged infringement of the ’808 patent through its past offerings for sale and continuing sales of its Creator™ products and products which depend upon or include the Creator™ technology.

8. In April of 1998, Plaintiff Clontech entered into licensing negotiations with Baylor with respect to certain technology covered by the ’808 patent (“the Elledge technology”). As part of those negotiations, it was necessary for Clontech to receive various materials and information from Baylor and BCMT.

9. Clontech agreed to use any information and/or materials it received from BCMT for purposes of evaluating its possible scientific and technical merits and its possible commercial potential.

10. Between July 1998 and December 1998, Clontech and Baylor unsuccessfully attempted to negotiate terms for a license to the technology covered by the ’808 patent.

11. On December 17, 1998, Baylor informed Clontech that the technology covered by the '808 patent would be licensed to another company and not to Clontech. (The '808 patent then issued on December 22, 1998).

12. Clontech, upon receiving notice from Baylor that they would not be granted a license to the '808 patent's technology, continued its prior efforts towards the independent development of its own proprietary rapid subcloning technology. These efforts resulted in the development of a novel methodology which Clontech commercialized as its Creator™ products and technology. Clontech's developmental efforts did not incorporate or otherwise include any information or materials received from Baylor and/or BCMT.

13. In 1999, as a result of its independent development efforts, Clontech commercially launched its Creator™ system for rapid subcloning of DNA. Clontech has also filed a U.S. Patent Application directed to this proprietary version of rapid subcloning technology. Clontech's developmental work and the achievement of the novel and proprietary Creator™ product(s) was accomplished independently of any information or materials received from Baylor and/or BCMT.

14. On or about December 5, 2001, Baylor and BCMT filed a Texas state court action in the 133<sup>rd</sup> Judicial District Court of Harris County, Texas, Cause No. 2001-61352 ("the State Action"), against Clontech for various causes of action which are factually and legally intertwined with the allegations of this Complaint. The State Action allegations include breach of contract, misappropriation of trade secrets, statutory theft of trade secrets, breach of fiduciary relationship and conversion. (A copy of the Petition is attached hereto as Exhibit B).

15. In the State Action, Baylor has alleged that certain biological materials, including specific plasmids and cell lines (which Baylor defined therein as the "Elledge trade secrets"), were employed by Clontech in the development of Clontech's Creator™ technology.

16. Baylor and BCMT have specifically alleged that: "Clontech's Creator system is based upon and makes use of the Elledge trade secrets, including Elledge technology, and will continue to use the trade secrets, including the Elledge technology, thereby causing irreparable harm to Baylor and BCMT." (Exhibit B at ¶ 16).

17. Baylor and BCMT have alleged the Elledge technology is covered by the '808 patent and that Clontech has made use of and continues to use the Elledge technology. As such, Baylor and BCMT have accused Clontech of infringing the '808 patent.

18. In its Prayer for Relief in the State Action, Baylor and BCMT seek several forms of relief which are normally available under the federal patent laws of Title 35 of the United States Code and the applicable Federal Circuit precedent. Such forms of relief include injunction, attorneys' fees, and actual and treble damages as specified in the federal patent laws at 35 U.S.C. §§ 283-285. (Cf. Exhibit B at pp. 9-11).

*This is equally available under state law*

19. Further, representatives of Baylor have publicly stated that Baylor intends to sue Clontech for infringement of the '808 patent.

20. As demonstrated in the foregoing paragraphs, Clontech has a reasonable apprehension that, as demonstrated by and in addition to the State Action, it will be sued for patent infringement by Baylor and BCMT based upon its marketing and sales of its proprietary Creator™ products. Hence, an immediate, real, and justiciable controversy exists between the parties which gives rise to this declaratory judgment action.



### **Allegation of Non-Infringement**

21. Clontech incorporates by reference the specific allegations of paragraphs 1-20.
22. Clontech has not infringed, and does not infringe, any valid claim of the '808 patent.
23. Clontech neither used the Elledge information or materials in its Creator™ technology nor did it base its Creator™ technology on any materials or information it received from Baylor or BCMT.
24. The development of Clontech's Creator™ technology was entirely independent of Clontech's interaction with Baylor and without any benefit of the Elledge information, technology or materials, and the Creator™ products do not fall within the scope of any of the '808 patent claims.

### **Allegation of Invalidity**

25. Clontech incorporates by reference the specific allegations of paragraphs 1-24.
26. On information and belief, the claims of the '808 patent are invalid under the patent laws of the United States, as codified in Title 35 of the United States Code including, but not limited to, §§ 102, 103 and 112.
27. On information and belief, the claims of the '808 patent are invalid under 35 U.S.C. § 112, ¶ 1 for, *inter alia*, failure to comply with the best mode requirement. Baylor and BCMT have admitted that it maintains information concerning the Elledge technology as a trade secret thereby violating its obligations under 35 U.S.C. § 112, ¶ 1.

28. On information and belief, the claims of the '808 patent are invalid as anticipated, derived from and/or obvious under 35 U.S.C. § 102/103 over the prior art.

**Request for Relief**

29. Clontech respectfully requests:

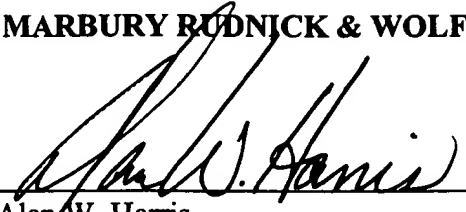
- a. a judgment declaring that Plaintiff has not infringed, and is not presently infringing, the '808 patent;
- b. a judgment declaring that the claims of the '808 patent are invalid;
- c. a judgment awarding its attorney fees pursuant to 35 U.S.C. § 285;
- d. a judgment awarding its costs (Fed. R. Civ. P. 54(d)); and
- e. any other relief the Court may deem appropriate under the circumstances.

Dated: January 4, 2002.

Respectfully submitted,

**PIPER MARBURY RUDNICK & WOLFE LLP**

By: \_\_\_\_\_

  
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**ATTORNEYS FOR DEFENDANT  
CLONTECH LABORATORIES, INC.**

2001-61352

ASSESSED
ENTERED <i>[Signature]</i>
VERIFIED <i>[Signature]</i>

CAUSE NO. \_\_\_\_\_

BAYLOR COLLEGE OF MEDICINE and  
BCM TECHNOLOGIES, INC.,

*Plaintiffs,*

v.

CLONTECH LABS, INC.,

*Defendant.*

IN THE DISTRICT COURT

HARRIS COUNTY, TEXAS

33 JUDICIAL DISTRICT

### PLAINTIFFS' ORIGINAL PETITION

Plaintiffs Baylor College of Medicine ("*Baylor*") and BCM Technologies, Inc. ("*BCMT*") complain of defendant Clontech Labs, Inc. ("*Clontech*") as follows:

#### PARTIES

1. Plaintiff Baylor is a nonprofit corporation organized and existing under the laws of the State of Texas having a principal place of business at Baylor Plaza, Houston, Texas 77030. Plaintiff BCMT is a Delaware corporation that maintains its principal place of business at 1709 Dryden Road, Suite 900, Houston, Texas 77030. BCMT is a wholly-owned subsidiary of Baylor responsible for licensing Baylor's technology.

2. Defendant Clontech is a Delaware corporation having its principal place of business at 1020 E. Meadow Circle, Palo Alto, California 94303. Because Clontech has not designated a registered agent for service of process in Texas, pursuant to § 17.044 of the Texas Civil Practice & Remedies Code, service may be effectuated by serving the Texas Secretary of State with the complaint, who shall then immediately mail a copy thereof to Clontech at its principal place of business.

## JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction in that more than the minimum jurisdictional amount is in controversy. Personal jurisdiction is proper as defendant Clontech is doing business within Texas, purposely directed tortious activity at Texas that caused harm in Texas, and entered into a contract with Texas residents requiring performance in whole or in part in this State.

4. Venue is proper in that this action centers on (i) contracts that were entered into in Harris County, Texas, which were performable, at least in part, in the County and (ii) torts that were committed, in whole or in part, in Harris County, Texas.

## PLAINTIFF BAYLOR

5. Baylor College of Medicine has earned a reputation as one of the leading medical universities. Baylor attracts students from around the world and is home to 668 medical students, 399 graduate students, 255 postdoctoral fellows, 125 allied health students, and 962 resident physicians pursuing specialty training. In conjunction with its training and schooling, Baylor offers patient care services through several of its Texas Medical Center affiliate hospitals, providing more than 131,000 inpatient visits and nearly 2 million outpatient visits annually.

6. In the past fiscal year, Baylor was ranked number one among universities and colleges in total and federally financed research and development expenditures in the biological sciences and thirteenth in National Institute of Health funding to medical schools. The college, with total research support of \$310 million, has more than 70 research and patient-care centers.

centers. The only private medical school in the Greater Southwest, Baylor is among the top 20 of the 125 U.S. medical schools in federal research funding.

7. Over the years, Baylor has expended considerable sums of money on research and development in subcloning of nucleic acid sequences at its Houston facilities in an effort to discover, improve and commercialize products related to identifying the functions of genes. As a result of its development efforts in the field of genomic research, Steve Elledge developed novel compositions and methods for rapid subcloning of DNA which provided a very quick and simple system of identifying genes ("*the Elledge technology*"). In 1997 Baylor applied for a patent covering some of the Elledge technology. The patent was assigned to Baylor and ultimately issued December 22, 1998 as U.S. Patent 5,851,808 ("*the '808 patent*").

8. Just prior to the '808 patent issuing, Elledge published an article disclosing some of the Elledge technology on November 19, 1998. Prior to this publication, the Elledge technology was kept confidential by Baylor as trade secrets, and was not known to either the public or the industries in which it might be exploited.

#### LICENSING THE ELLEDGE TECHNOLOGY

9. In April of 1998, Baylor entered into licensing negotiations with Clontech over the Elledge technology. As part of those negotiations, it was necessary for Baylor to transfer various trade secrets, information, and material to Clontech. Before this was done, Clontech signed a Confidential Disclosure Agreement with BCMT and a Material Transfer Agreement with Baylor. Subsequent to these two contracts, Baylor disclosed the Elledge technology to Clontech including the then pending patent application covering part of the technology, and

allowed them free communication with Dr. Elledge. Approximately two weeks after the agreements were signed the Elledge technology materials were sent to Clontech including:

- (1) a uni-vector plasmid (pUNI10);
- (2) a recipient plasmid (e.g.: pHB2-Gst, a bacterial Gst fusion plasmid with a lox site);
- (3) a recombinase expression plasmid (e.g.: pQLI23, the Gst-cre expression plasmid); and
- (4) the cell lines for conducting the studies (BUN13 and BUN15)

The listed information and materials, together with all other information and materials furnished to Clontech shall hereafter be referred to as the "*Elledge trade secrets*".

10. Under the terms of the Confidential Disclosure Agreement and Material Transfer Agreement, Clontech agreed not to disclose any of the Elledge trade secrets, including the Elledge technology, unless such information became publicly available, and to use the materials only to evaluate the technology. Clontech also agreed that all rights to any technology developed via use of the Elledge trade secrets belonged to Baylor. Specific key provisions of the Confidential Disclosure Agreement include:

- (1) Clontech may only use the confidential information for the "sole purpose of evaluating the scientific and technical merit and commercial potential thereof." [¶ 1]
- (2) Clontech acknowledges BCMT is providing them "trade secrets, know-how and confidential data or materials." [*Id.*]
- (3) Certain Clontech obligations under the agreement cease if the information becomes public through no fault of Clontech. [¶ 3(a)]
- (4) If there is a breach, "the damage will be substantial, although difficult to quantify, and money damages will not afford an adequate remedy. Therefore . . . BCMT shall have the right to . . . [a] temporary or permanent injunction." [¶ 6]

11. Key provisions of the Material Transfer Agreement include:
- (1) the research material "will only be used [by Clontech] for non-commercial evaluation of the Research Material . . . and [to] determine suitability for potential license arrangement. Any and all other studies or uses are expressly prohibited and may not be pursued by the Recipient . . . . *The Research Materials will not be used for commercial purposes . . . .*" [¶ 2] (emphasis added).
  - (2) "When the Research Project" is completed . . . Recipient will destroy the Research Material and advise BCM of such destruction." [¶ 5]
  - (3) "BCM hereby retains and Recipient hereby grants BCM all rights in and to all inventions made through the use of the Research Material. Recipient agrees that it will promptly disclose to BCM all inventions made through the use of the Research Material and will assign such rights to BCM, subject to the right of the Recipient to a non-exclusive license to use the same for research purposes." [¶ 6]
12. Between July 1998 and December 1998, Clontech and Baylor attempted without success to negotiate terms for a license to the Elledge technology.
13. On December 17, 1998 Baylor advised Clontech that the technology would be licensed to a different company.

#### DEFENDANT CLONTECH

14. Upon notice that they would not be the licensee, Clontech expressed extreme displeasure. On or about December 18, 1998, in a letter, Kenneth Fong, the Founder and CEO of Clontech, and two other Clontech employees stated to Baylor that Clontech had already begun commercial product development using the Elledge technology.
15. Approximately one year later, Clontech launched its 'Creator system for rapid subcloning of DNA, and filed patent applications on their system. The Clontech product is similar to the Elledge technology disclosed by Baylor.



16. Upon information and belief, Clontech's Creator system is based upon and makes use of the Elledge trade secrets, including the Elledge technology, and will continue to use the Elledge trade secrets, including the Elledge technology, thereby causing irreparable harm to Baylor and BCMT.

#### COUNT I - BREACH OF CONTRACT

17. For this cause of action, Baylor and BCMT repeat and adopt all allegations contained in paragraphs 1 through 16 above.

18. Defendant Clontech has breached its contractual obligations (expressed and implied) under the Confidential Disclosure Agreement and Material Transfer Agreement by, *inter alia*, commercially exploiting the Elledge trade secrets, including the Elledge technology.

19. Defendant Clontech has breached its contractual obligations (expressed and implied) under the Confidential Disclosure Agreement and Material Transfer Agreement by, *inter alia*, failing to destroy the Elledge trade secrets upon completion of the evaluation period and for failing to notify Baylor of such destruction.

20. Defendant Clontech has breached its contractual obligations (expressed and implied) under the Confidential Disclosure Agreement and Material Transfer Agreement by, *inter alia*, failing to disclose to Baylor all inventions made through the use of the Elledge trade secrets.

21. Defendant Clontech has breached its contractual obligations (expressed and implied) under the Confidential Disclosure Agreement and Material Transfer Agreement by,

*inter alia*, failing to assign to Baylor all rights in and to all inventions made through the use of the Elledge trade secrets.

### **COUNT II - MISAPPROPRIATION OF TRADE SECRETS**

22. Paragraphs 1 through 21 are specifically incorporated into this cause of action.
23. Baylor and BCMT are, and at all times mentioned in this petition have been, engaged in an effort to develop and commercialize the technology at issue in this litigation.
24. At the time of Clontech's misappropriation, the Elledge trade secrets, including the Elledge technology were not known to the public or the industry in which they might be used. The Elledge trade secrets, including the Elledge technology were developed at considerable expense to Baylor, and they constituted valuable trade secrets that would give a competitive advantage to anyone commercially exploiting them.
25. Clontech intentionally and wrongfully misappropriated trade secrets from Baylor and BCMT for the purpose of commercially using them.

### **COUNT III - CONVERSION**

26. Paragraphs 1 through 25 are specifically incorporated into this cause of action.
27. Clontech has unlawfully asserted dominion and control over property owned by Baylor and BCMT by:
- a. gaining access to Baylor and BCMT's confidential and trade secret information and materials; and

- b. taking Baylor and BCMT's confidential information, trade secrets, and materials and converting them for its own use.

28. Upon information and belief the conversion by Clontech has been willful and malicious, with an attempt to cause the harm alleged.

#### **COUNT IV - BREACH OF FIDUCIARY RELATIONSHIP**

29. Paragraphs 1 through 28 are specifically incorporated in this cause of action.

30. Clontech undertook a relationship of trust and confidence with Baylor and BCMT whereby Clontech owed Baylor and BCMT fiduciary duties, including duties of good faith and fair dealing, loyalty, and full disclosure to Baylor and BCMT.

31. Clontech has breached its fiduciary duties to Baylor and BCMT by using their confidential information, trade secrets, and materials.

#### **COUNT V - STATUTORY CLAIM FOR THEFT OF TRADE SECRET**

32. Paragraphs 1 through 31 are specifically incorporated in this cause of action.

33. Clontech intentionally and knowingly misappropriated the confidential information, trade secrets, and materials of Baylor and BCMT and adopted them as its own.

34. Pursuant to § 134.003 of Texas Civil Practice & Remedies Code, and § 31.05 of the Texas Penal Code, Clontech should be held liable for theft of trade secrets. Pursuant to § 134.005(b) of Texas Civil Practice & Remedies Code, plaintiffs are also entitled to attorneys' fees and costs.

### **JURY DEMAND**

35. Baylor and BCMT demand a jury trial as to all matters in this action, whether currently pleaded or as may be later pleaded, to which it may be entitled under the Constitution, laws, or statutes of the United States, or any applicable state constitution, law, or statute, or at common law.

### **PRAYER FOR RELIEF**

Wherefore, Baylor and BCMT pray for relief as follows:

(1) **Injunctive Relief**

Granting a permanent injunction against defendant, its agents, representatives, employees and servants and all persons and entities in concert or participation with it, and

- a. ordering it to immediately turn over to plaintiffs (i) all Elledge trade secrets and derived information in whatever form (including all documents, records, laboratory notebooks, computer disks, files, correspondence, mail, and other materials), and (ii) the Creator system and derived information in whatever form (including all documents, records, laboratory notebooks, computer disks, files, correspondence, mail, and other materials);
- b. ordering that Clontech cease and refrain from (i) using any of the Elledge trade secrets, including the Elledge technology, or any derived information or technology and (ii) using, marketing, selling, distributing or otherwise exploiting the Creator system or any derived information or technology;

- c. ordering that Clontech cease and refrain from engaging in any conduct or activity which has the effect of interfering with terminating or diminishing any of plaintiffs' contracts and/or business relationships with prospective licensees; and
- d. ordering that Clontech cease and refrain from destroying or altering (i) any all Elledge trade secrets, including the Elledge technology, as well as any and all derived information or technology, in whatever form (such as documents, records, laboratory notebooks, computer disks, files, correspondence, mail, and other materials) and (ii) the Creator system and any derived information or technology, in whatever form.
- (2) Actual damages in an amount to be determined at trial.
- (3) Punitive damages in an amount of at least three times the amount of actual damages awarded;
- (4) An equitable order requiring defendant to disgorge to plaintiffs the full amount of all royalties, licensing fees, sales, and profits it has collected or retained in connection with (i) the Elledge trade secrets and any derived information or technology and (ii) the Creator system and any derived information or technology;
- (5) An assignment of all right and interest over all data, work product, intellectual property (including, but not limited to all patents and patent applications), personal property, trade secrets which are related to the Elledge trade secrets, the Creator system, or any derived information or technology.

(6) Reasonable and necessary attorneys' fees incurred by plaintiffs in connection with this action, pursuant to Chapter 38 of the Texas Civil Practice & Remedies Code and other applicable law;

(7) Prejudgment and post-judgment interest at the highest rate(s) allowed by law;

(8) Costs of court; and

(9) Such other and further relief that this Court may deem just and proper.

Respectfully submitted,

VINSON & ELKINS L.L.P.

  
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*Attorneys for Plaintiffs  
Baylor College of Medicine  
and BCM Technologies, Inc.*



**EXPEDITED PROCEDURE REQUESTED  
PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Elledge et al.	)	Examiner: James S. Ketter
	)	
USSN: 09/122,384	)	Art Unit: 1636
	)	
For: Rapid Subcloning Using Site-Specific Recombination	)	Filed: July 24, 1998
	)	

**PROTEST AGAINST PENDING APPLICATION UNDER 37 C.F.R. § 1.291**

Honorable Commissioner for Patents  
Mail Stop Petitions  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Clontech Laboratories, Inc. ("Clontech") hereby petitions the Commissioner to initiate a protest against pending application number 09/122,384 under 37 C.F.R. § 1.291.

**I. SUBJECT MATTER DISCLOSED IN U.S. SERIAL NO. 09/122,384 IS THE SUBJECT MATTER OF LITIGATION**

Clontech is in litigation against BCM Technologies, Inc. and Baylor College of Medicine (collectively "BCM"), who are believed to be the assignee of USSN 09/122,384 ("the '384 application") over an alleged theft of trade secrets. The case is in the Texas 133<sup>rd</sup> Judicial District Court in Harris County, Texas, Cause No. 2001-61352.

Clontech repeatedly requested all documents concerning U.S. Patent No. 5,851,808 ("the '808 patent"), the patent that issued from the parent application to the '384 application, which document requests encompass any continuations and continuations-in-part thereof. Clontech

again explicitly requested all documents related to any continuation applications following the April 14, 2003 deposition of Charles Lipsey (the April 14, 2003 letter requesting such documents is attached as Ex. 1 hereto), during which BCM's questioning implied that one or more continuation applications may be pending. BCM has repeatedly ignored such demands and failed to provide such documents until recently, after the close of discovery in the pending litigation. BCM's conduct is the subject of a motion to compel in the Texas Court.

On May 6, 2003, after the close of discovery, litigation counsel for BCM belatedly provided a letter to Clontech enclosing a Notice of Allowability of USSN 09/122,384, which was mailed in late April (Ex. 2 hereto). BCM also provided other documents to Clontech on May 16 and 17, 2003, indicating information disclosed to the Office.

The information BCM provided to Clontech does not indicate that BCM alerted the Office to the case *Baylor College of Medicine et al. v. Clontech Laboratories, Inc. v. Invitrogen Corp.* case in the Texas 133<sup>rd</sup> Judicial Court in Harris County, Texas. (A copy of Plaintiff's First Amended Petition is attached hereto as Ex. 3). This case is related to the subject matter of the '384 application and the '808 patent. Nor does the information provided by BCM indicate that BCM alerted the Office to the declaratory judgment action filed in the U.S. District Court for the Southern District of Texas on January 4, 2002, alleging *inter alia*, the invalidity and non-infringement of the '808 patent. (A copy of the Complaint For Declaratory Judgment is attached hereto as Ex. 4). The latter federal case was only recently dismissed on April 7, 2003 (Ex. 5), as a result of BCM's motion to dismiss along with its Covenant Not To Assert The '808 Patent (Ex. 6), which were also not brought to the attention of the Office.

Under 37 C.F.R. § 1.56, applicants and applicants' representatives must disclose (1) the existence of litigation and (2) any material information arising from that litigation related to the



subject matter of the patent application, including, for example, deposition testimony. *See, e.g.*, MPEP 2001.06(c); *Environ Products v. Total Containment, Inc.*, 43 U.S.P.Q. 2d 1288 (E.D. Pa. 1997); *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 68 F. Supp.2d 508 (D.N.J. 1999).

The documents BCM recently provided to Clontech from the PTO prosecution include disclosures of some prior art to the Office, but do not include any disclosure of the ongoing litigation and do not include any disclosure of critical admissions that occurred in depositions taken during discovery. The submitted documents also do not include any disclosure of the dismissed litigation and covenant not to assert the '808 patent.

## **II. THIS PROTEST INVOLVES INFORMATION THAT CANNOT BE ADEQUATELY ADDRESSED WITH REEXAMINATION**

Our request for a Protest can only be addressed before issuance because the standard and type of prior art that may be considered will change after issuance. During examination, the Office need only show by a preponderance of the evidence that an application is unpatentable. Once a U.S. patent is issued, any challenge must be supported by clear and convincing evidence. While an issued U.S. patent can be reexamined, a reexamination can only consider patents and printed publications and only address issues arising under sections 102 or 103 of Title 35. BCM should not be permitted to benefit from its refusal to disclose information to the USPTO and to Clontech in a timely manner.

Clontech is bound by a protective order in the ongoing Texas litigation. This protective order bars Clontech from disclosing BCM information and deposition transcripts if BCM has designated them as confidential. BCM has utilized this protective order to designate much of the information disclosed as confidential and has designated all of its witnesses' deposition

testimony as confidential, except that of Dr. Liu. Consequently, Clontech cannot describe any admissions that might be present in other depositions that have occurred, including the depositions of Drs. Elledge and Kreuzer and Ms. Li. Nevertheless, Clontech can disclose that the deposition transcript which BCM did not designate as confidential – that of Dr. Liu -- contains admissions that are material to the patentability of the claims that were provided in the preliminary amendment of October 3, 2002. Claim numbers corresponding to those claims have now been allowed.

The deposition of Dr. Liu admits that at the time of filing of the application that led to the '808 patent (and therefore, necessarily before filing the '384 application therefrom), GST fusion proteins were known and the Cre enzyme was known:

Q: Okay. Now, GST fusion proteins were known in the art prior to your work, correct?

A: Correct.

Q. And the Cre enzyme itself was known in the art prior to your work, correct?

A. Correct.

Q. And am I correct in understanding that the Cre recombinases [sic recombinase], the Cre enzyme, its ability to recombine loxP site [sic sites] was also known in the art, correct?

A. Correct.

(Liu Dep. at 15:23-16:8, Ex. 7).

These admissions appear material to the patentability of for example claims 43, 46, 48, 49, 52-54, 56 and 63 as those claims appear in the Preliminary Amendment that BCM disclosed to Clontech. These claim numbers are those that appear to correspond to the allowed claims on the Notice of Allowability. (Ex. 1).

While Clontech cannot provide information marked confidential to the Office, BCM can provide this information to the PTO. This information can be supplied as part of BCM's Duty of Disclosure under Rule 1.56, or it can be provided in response to a direct request from the Examiner under 37 C.F.R. § 1.105.

The review under 37 C.F.R. § 1.291 represents the PTO's last opportunity to consider information contained in the deposition transcripts. Once the 09/122,384 patent issues, the PTO will not be able to provide any meaningful review of the deposition transcript admissions. As indicated by Assistant Deputy Commissioner Kunin, "[t]he PTO has an obligations to issue patents that meet the statutory requirements for patentability." *Blacklight Power, Inc. v. Rogan*, 295 F.3d 1269, 1271 (Fed. Cir. 2002) (affirming the PTO's decision to cancel issuance of a patent after allowance and after the issue fee was paid). Moreover, the PTO is vested with broad "latitude to withdraw an application from issue without a final determination of unpatentability when the exigencies of time do not allow for such determination." *Id.* at 1272.

### **III. THE PTO SHOULD PERMIT THE INITIATION OF A PROTEST OR STAY ISSUANCE OF A PATENT ON THE '384 APPLICATION**

The PTO should initiate a Protest, based on the failure of BCM to alert the agency to ongoing litigation related to the '384 application and the failure of BCM to provide the PTO with material deposition admissions. In the alternative, the PTO should stay issuance of the '384 application until the Judge in the Texas 133<sup>rd</sup> Judicial District Court rules on Clontech's Motion to De-designate Certain Deposition Admissions Material to the Patentability Determination of Baylor Patent Application Claims and permits the PTO Examiner to review the deposition testimony. Clontech is presently preparing a motion to de-designate the transcripts or portions thereof that contain admissions material to the patentability of the '384 application. This motion will be submitted to the Judge, who will determine if this information can be provided to the PTO to permit the PTO to perform its mission.

This Protest has been served upon applicants via their representative in accordance with 37 CFR § 1.248 as well as being filed in duplicate with the PTO. Proof of service is attached as Exhibit 8 hereto.

The U.S. Patent and Trademark Office is hereby authorized to charge any fees that may be required in conjunction with this submission to Deposit Account Number 50-2228.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Scott A. Chambers", is written over a horizontal line.

Scott A. Chambers  
Reg. No. 37,573

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April 14, 2003

Richard J. Oparil  
(202) 457-6496  
Roparil@pattonboggs.com

***VIA FACSIMILE***

David P. Blanke, Esq.  
Vinson & Elkins LLP  
The Terrace 7  
2801 Via Fortuna  
Suite 100  
Austin, Texas 78746

Re: *Baylor College of Medicine, et al. v. Clontech Laboratories, Inc. v. Invitrogen Corp.*  
Cause No. 2001-61352

Dear David:

Further to my request at the conclusion of the April 14, 2003 deposition of Charles Lipsey, please provide us with the following documents immediately:

- (1) the exhibits marked at Ruo Bo Zhang's deposition, and
- (2) all documents relating to all continuations from or other U.S. patent applications related to the '808 patent

With regard to the latter request, we are aware that at least one such continuation application exists. In particular, as shown on the enclosed Patent Application Information Retrieval search of continuity data, U.S. Patent Application 09/122,384 is a pending continuation application from the application that matured into the '808 patent. Clontech long ago requested information pertaining to Baylor's '808 patent. Baylor chose to object to providing such information and required Clontech to file a (pending) Motion to Compel. As demonstrated in the questions you posed to Mr. Lipsey, these documents are relevant to the claims and defenses in this action.

Please let us know when we may expect to receive the requested documents.

Very truly,

A handwritten signature in black ink, appearing to read 'R. Oparil', written over the words 'Very truly,'.

Richard J. Oparil  
Enclosures

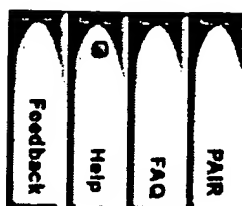
cc: Glenn A. Ballard, Jr., Esq.



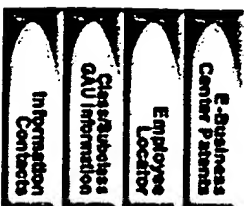
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## PATENT APPLICATION INFORMATION RETRIEVAL



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Search results for patent number: 5,851,808			
Application Number:	08/864,224	Class / Sub-Class:	435/172.300
Filing or 371(c) Date:	02-28-1997	Location:	-
Issue Date of Patent:	12-22-1998	Status:	-
Examiner Name:	RAILEY, JOHNNY	Group Art Unit:	1636
Earliest Publication No.:	-	Attorney Docket	BCM-02681
Earliest Publication	-	Customer Number:	-
Confirmation Number:	6512		

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Description	Parent Number	Parent Filing or 371(c) Date	Parent Status
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Child Continuity Data	
09/122,384 filed on 07-24-1998 which is Pending claims the benefit of 08/864,224	

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Search results for application number: 08/864,224			
Filing or 371(c) Date:	02-28-1997	Class / Sub-Class:	435/172.300
Issue Date of Patent:	12-22-1998	Location:	-
Examiner Name:	RAILEY, JOHNNY	Status:	-
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5 MAY -6 P1:59

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dblank@velaw.com

## FACSIMILE TRANSMITTAL PAGE

DATE: May 6, 2003

Glenn A. Ballard, Jr.  
Bracewell & Patterson

FAX: 713.221.1212

PHONE: 713.223.2900

TO: Marc Labgold  
Kevin M. Bell  
Patton Boggs (VA)

FAX: 703.744.8001

PHONE: 703.744.8000

TO: Richard J. Oparil  
Patton Boggs (DC)

FAX: 202.457.6315

PHONE: 202.457.6000

PAGES: 14 (including this transmittal page)

CLIENT/MATTER: INV850/13000

FROM: David P. Blanke

MESSAGE: David Blanke's 05/06/03 letter further responding to 04/14/03 Oparil letter.

Hard Copy Follows ☐ Yes ☒ No

### CONFIDENTIALITY NOTICE:

The information contained in this FAX may be confidential and/or privileged. This FAX is intended to be reviewed initially by only the individual named above. If the reader of this TRANSMITTAL PAGE is not the intended recipient or a representative of the intended recipient, you are hereby notified that any review, dissemination or copying of this FAX or the information contained herein is prohibited. If you have received this FAX in error, please immediately notify the sender by telephone and return this FAX to the sender at the above address. Thank you.

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May 6, 2003

*By Fax*

Mr. Richard J. Oparil  
Panton Boggs L.L.P.  
2550 M Street NW  
Washington, DC 20037

Re: *Baylor College of Medicine, et al. v. Clontech Laboratories, Inc.;*  
Cause No. 2001-61352

Dear Richard:

I am further responding to your April 14 letter. Earlier I wrote regarding the Ruobo Zhang exhibits. As to the '808 continuations, we will be producing the non-privileged documents on this issue. In the meantime, I am providing the accompanying preliminary amendment and notice of allowance from the PTO.

Very truly yours,

David P. Blanke

attachment

c: Glenn A. Ballard, Jr. (by fax; w/att.)  
Kevin Bell (by fax; w/att.)  
Tracey B. Davies [Firm; w/o att.]  
M. Michelle Muller [Firm; w/o att.]  
Jason M. Powers [Firm; w/o att.]



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: ASSISTANT COMMISSIONER FOR PATENTS  
Washington, D.C. 20231

APPLICATION NO/ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
--------------------------------	-------------	---	---------------------

EXAMINER
----------

ART UNIT	PAPER
----------	-------

47

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

--See attached--

**Notice of Allowability**

Application No.

09/122,384

Examiner

James S. Ketter

Applicant(s)

ELLEDGE ET AL.

Art Unit

1836

**- The MAILING DATE of this communication appears on the cover sheet with the correspondence address-**  
 All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment of 10/3/02 and the IDS of 3/4/03.
2. ☒ The allowed claim(s) is/are 43-68.
3. ☒ The drawings filed on 20 March 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- |   |  |
|---|--|
| <input type="checkbox"/> Notice of References Cited (PTO-892)   | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____    |
| <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. <u>70, 72 &amp; 73.</u> | 6 <input type="checkbox"/> Examiner's Amendment/Comment                    |
| <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material                | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9 <input type="checkbox"/> Other   |

**JAMES KETTER**  
**PRIMARY EXAMINER**



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Assistant Commissioner for Patents and Trademarks  
Washington, D.C. 20530

NOTICE OF ALLOWANCE AND FEE(S) DUE

21566 7590 04/22/2003  
VINSON & ELKINS, L.L.P.  
1001 FANNIN STREET  
2300 FIRST CITY TOWER  
HOUSTON, TX 77002-6760

RECEIVED

APR 28 2003

IR-Bracket Office  
Vinson & Elkins

EXAMINER  
KETTER, JAMES S

ART UNIT CLASS-SUBCLASS

1636

415-006000

DATE MAILED: 04/22/2003

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/122,384	07/24/1998	STEPHEN J. ELLEDGE	RAY1364-010CLP	4340

TITLE OF INVENTION: RAPID SUBCLONING USING SITE-SPECIFIC RECOMBINATION

APPL. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1300	\$0	\$1300	07/22/2003

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status.  
See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

## PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Box ISSUE FEE  
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address, and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Please Legibly Print - with any abbreviations, if any) 31546 7390 04/22/2003

VINSON & ELKINS, L.L.P.  
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 HOUSTON, TX 77002-6760

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission  
 I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above, or being facsimile transmitted to the USPTO, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/122,184	07/24/1998	STEPHEN J. ELLEDGE	BAY1364-010CIP	4340

TITLE OF INVENTION: RAPID SUBCLONING USING SITE-SPECIFIC RECOMBINATION

APPL. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1300	\$0	\$1300	07/22/2003

EXAMINER	ART UNIT	CLASS-SUBCLASS
KETTER, JAMES S	1636	435-006000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.  
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 01-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE (CITY AND STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) ☐ individual ☐ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:

- ☐ Issue Fee  
☐ Publication Fee

☐ Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s):

☐ A check in the amount of the fee(s) is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature)

(Date)

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant, a registered attorney or agent, or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 15 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/123,384	07/24/1996	STEPHEN J. ELLEDGE	BAY1364-010CIP	6340
21586	7590	04/22/2003	EXAMINER	
VINSON & ELKINS, L.L.P. 1001 FANNIN STREET 2300 FIRST CITY TOWER HOUSTON, TX 77002-6760			KETTER, JAMES S	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 04/22/2003				

**Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**  
(application filed on or after May 29, 2000)

The patent term adjustment to date is 0 days. If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the term adjustment will be 0 days.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (<http://pair.uspto.gov>)

Any questions regarding the patent term extension or adjustment determination should be directed to the Office of Patent Legal Administration at (703)305-1383.



**UNITED STATES PATENT AND TRADEMARK OFFICE**

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20531  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/122,384	07/24/1998	STEPHEN J. ELLEDGE	RAY1364-010CIP	4340
21584	7590	04/22/2003	EXAMINER	
VINSON & ELKINS, L.L.P. 1001 FANNIN STREET 2300 FIRST CITY TOWER HOUSTON, TX 77002-6760 UNITED STATES			KETTER, JAMES S	
			ART ID#	PAPER NUMBER
			1036	
DATE MAILED: 04/22/2003				

**Notice of Fee Increase on January 1, 2003**

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after January 1, 2003, then the amount due will be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there will be an increase in fees effective on January 1, 2003. See Revision of Patent and Trademark Fees for Fiscal Year 2003: Final Rule, 67 Fed. Reg. 70847, 70849 (November 27, 2002).

The current fee schedule is accessible from: <http://www.uspto.gov/main/howtofees.htm>.

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of the fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filed on or after January 1, 2003 (or mailed with a certificate of mailing on or after January 1, 2003), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

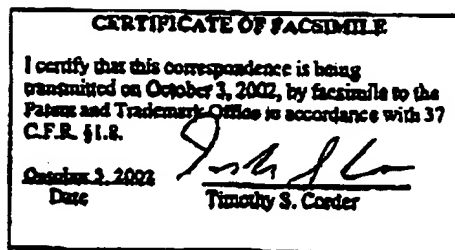
Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

**Vinson & Elkins**  
ATTORNEYS AT LAW

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Timothy S. Corder  
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tcorder@vclaw.com

October 3, 2002



Assistant Commissioner for Patents  
Washington, D.C. 20231

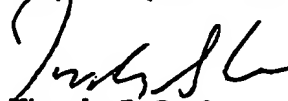
Re: U.S. Patent Application SN 09/122,384 "Rapid Subcloning Using Site-Specific Recombination," by Elledge et al.  
Attorney Docket No.: BAY136/4-010CIP/36000; Client Ref.: OTA # 97-27  
Confirmation No. 4340

Sir:

Enclosed for filing in the above-referenced patent application is a Preliminary Amendment for filing in the above-referenced patent application.

It is believed that no fee is due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Assistant Commissioner is authorized to appropriately deduct or credit the requisite amount from Vinson & Elkins L.L.P. deposit account No. 22-0365/BAY136/4-010CIP/36000.

Respectfully submitted,

  
Timothy S. Corder  
Reg. No. 38,414

9282:5588

Enclosure

11728\_1.DOC

AUSTIN • BEIRING • DALLAS • HOUSTON • LONDON • MOSCOW • NEW YORK • SINGAPORE • WASHINGTON, D.C.



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Stephen J. Elledge et al.

Serial No.: 09/122,384

Filed: July 24, 1998

For: Rapid Subcloning Using Site-Specific  
Recombination

Group Art Unit: 1636

Examiner: J. Ketter

Any. Dkt. No.: BAY136/4-10CIP/36000

Confirmation No. 4340

**CERTIFICATE OF FACSIMILE**

I certify that this correspondence is being transmitted on  
October 3, 2002, by facsimile to the Patent and Trademark  
Office in accordance with 37 C.F.R. §1.8.

October 3, 2002

*Timothy S. Corder*  
Timothy S. Corder

**PRELIMINARY AMENDMENT**

**VIA FACSIMILE NO. 703-746-5155**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In advance of prosecution, the Examiner is requested to please amend the above-captioned application as follows:

**AMENDMENT**

**A. In the Claims:**

Please cancel all pending claims, i.e. claims 1-20, 26, 30-35, and 37-42, and enter the following new claims:

43. A composition comprising a glutathione-S-transferase-Cre-recombinase fusion polypeptide.

44. The composition of claim 43, wherein the polypeptide has an amino acid sequence according to SEQ ID NO:11.
45. The composition of claim 43, wherein the composition comprises an enzyme activity with a Cre recombinase efficiency of about 16.8% per microgram of protein.
46. An isolated nucleic acid molecule comprising a coding region wherein the coding region encodes a glutathione-S-transferase-Cre-recombinase fusion polypeptide.
47. The nucleic acid molecule of claim 46, wherein the coding region comprises the nucleic acid sequence of SEQ ID NO:10.
48. The nucleic acid molecule of claim 46, wherein the isolated nucleic acid molecule is an expression vector.
49. The nucleic acid molecule of claim 46, wherein the coding region is operatively linked to a promoter effective to direct expression of a glutathione-S-transferase-Cre recombinase fusion polypeptide.
50. The nucleic acid molecule of claim 49, wherein the promoter is an inducible promoter.
51. The nucleic acid of claim 50, wherein the promoter is the *lac* promoter.
52. A host cell comprising the nucleic acid molecule of claim 46.
53. A host cell comprising the nucleic acid molecule of claim 49.
54. The host cell of claim 53, wherein the host cell expresses a Cre recombinase activity.

55. The host cell of claim 53, further defined as an E. coli cell.
56. A bacterial cell engineered to express a glutathione-S-transferase-Cre-recombinase fusion polypeptide.
57. The bacterial cell of claim 56, wherein the polypeptide has an amino acid sequence according to SEQ ID NO:11.
58. A method of producing a glutathione-S-transferase-Cre-recombinase fusion polypeptide comprising:  
  
obtaining an expression vector comprising a coding region encoding a glutathione-S-transferase-Cre-recombinase fusion polypeptide operatively linked to a promoter;  
  
transforming or transfecting the vector into a cell; and  
  
growing the cell under conditions effective to express a glutathione-S-transferase-Cre-recombinase fusion polypeptide.
59. The method of claim 58, further comprising isolating the glutathione-S-transferase-Cre-recombinase fusion polypeptide.
60. The method of claim 59, wherein isolating the polypeptide comprises glutathione affinity chromatography.
61. A method of recombining nucleic acid segments, wherein each segment comprises a *lox* site specific recombinase site, the method comprising contacting the nucleic acid segments with a glutathione-S-transferase-Cre-recombinase fusion polypeptide.
62. The method of claim 61, wherein the polypeptide has an amino acid sequence according to SEQ ID NO:11.

63. A composition comprising a glutathione-S-transferase-Cre-recombinase fusion polypeptide and one or more nucleic acid molecules, wherein the nucleic acids comprise a site specific recombinase site.
64. The composition of claim 63, wherein at least one of said nucleic acid molecules comprises a lox recombination site upstream in a 5' to 3' orientation from an amino acid encoding region.
65. The composition of claim 63, wherein at least one of said nucleic acid molecules comprises a transcription regulatory element upstream in a 5' to 3' orientation of a lox recombinase site.
66. The composition of claim 64 wherein the lox recombinase site is a *loxP*, *loxP2*, *loxP3*, *loxP23*, *loxP511*, *loxB*, *loxC2*, *loxL*, *loxR*, *lox486*, *lox4117*, or *loxH* site.
67. The composition of claim 65 wherein the lox recombinase site is a *loxP*, *loxP2*, *loxP3*, *loxP23*, *loxP511*, *loxB*, *loxC2*, *loxL*, *loxR*, *lox486*, *lox4117*, or *loxH* site.
68. The composition of claim 64, wherein the amino acid encoding region is a member of a nucleic acid library.

## II. REMARKS

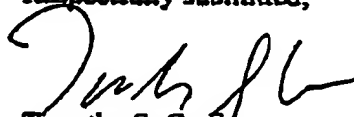
The claims in this preliminary amendment do not add new matter to the application and their entry is therefore respectfully requested. Support for the claims may be found throughout the Specification and at least in Example 3 found on page 47.

## IV. CONCLUSION

Applicants respectfully submit that the present application and all claims are in condition for immediate allowance and early notice to such effect is earnestly solicited. If, in the opinion of the Examiner, a phone call may help expedite prosecution of this application, the Examiner is invited to contact the undersigned representative at (512) 542-8446.

It is believed that no fee is due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Assistant Commissioner is authorized to deduct said fees from Vinson & Elkins L.L.P. Deposit Account No. 22-0365/BAY136/4-10CIP/36000.

Respectfully submitted,



Timothy S. Corder  
Reg. No. 38,414  
Agent for Applicant

Vinson & Elkins L.L.P.  
2300 First City Tower  
1001 Fannin  
Houston, Texas 77002-6760  
512/542-8446

Date: October 3, 2002

CAUSE NO. 2001-61352

BAYLOR COLLEGE OF MEDICINE and  
BCM TECHNOLOGIES, INC.,

*Plaintiffs,*

v.

CLONTECH LABS, INC.,

*Defendant.*

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§

IN THE DISTRICT COURT

HARRIS COUNTY, TEXAS

133RD JUDICIAL DISTRICT

**PLAINTIFFS' FIRST AMENDED PETITION**

Plaintiffs Baylor College of Medicine ("*Baylor*") and BCM Technologies, Inc. ("*BCMT*") complain of defendant Clontech Labs, Inc. ("*Clontech*") as follows:

**PARTIES**

1. Plaintiff Baylor is a nonprofit corporation organized and existing under the laws of the State of Texas having a principal place of business at Baylor Plaza, Houston, Texas 77030. Plaintiff BCMT is a Delaware corporation that maintains its principal place of business at 1709 Dryden Road, Suite 900, Houston, Texas 77030. BCMT is a wholly-owned subsidiary of Baylor responsible for licensing Baylor's technology.

2. Defendant Clontech is a Delaware corporation having its principal place of business at 1020 E. Meadow Circle, Palo Alto, California 94303. It has already entered an appearance and therefore may be served through its counsel of record in the manner indicated below.

**JURISDICTION AND VENUE**

3. This Court has subject matter jurisdiction in that more than the minimum jurisdictional amount is in controversy. Personal jurisdiction is proper as defendant Clontech is doing business within Texas, purposely directed tortious activity at Texas that caused harm in

Texas, and entered into a contract with Texas residents requiring performance in whole or in part in this State.

4. Venue is proper in that this action centers on (i) contracts that were entered into in Harris County, Texas, which were performable, at least in part, in the County and (ii) torts that were committed, in whole or in part, in Harris County, Texas.

#### **PLAINTIFF BAYLOR**

5. Baylor College of Medicine has earned a reputation as one of the leading medical universities. Baylor attracts students from around the world and is home to 668 medical students, 399 graduate students, 255 postdoctoral fellows, 125 allied health students, and 962 resident physicians pursuing specialty training. In conjunction with its training and schooling, Baylor offers patient care services through several of its Texas Medical Center affiliate hospitals, providing more than 131,000 inpatient visits and nearly 2 million outpatient visits annually.

6. In the past fiscal year, Baylor was ranked number one among universities and colleges in total and federally financed research and development expenditures in the biological sciences at and thirteenth in National Institute of Health funding to medical schools. The college, with total research support of \$310 million, has more than 70 research and patient-care centers. The only private medical school in the Greater Southwest, Baylor is among the top 20 of the 125 U.S. medical schools in federal research funding.

7. Over the years, Baylor has expended considerable sums of money on research and development in subcloning of nucleic acid sequences at its Houston facilities in an effort to discover, improve and commercialize products related to identifying the functions of genes. As a result of its development efforts in the field of genomic research, Steve Elledge developed novel compositions and methods for rapid subcloning of DNA which provided a very quick and simple

system of identifying genes ("*the Elledge technology*"). In 1997 Baylor applied for a patent covering some of the Elledge technology. The patent was assigned to Baylor and ultimately issued December 22, 1998 as U.S. Patent 5,851,808 ("*the '808 patent*").

8. Just prior to the '808 patent issuing, Elledge published an article disclosing some of the Elledge technology on November 19, 1998. Prior to this publication, the Elledge technology was kept confidential by Baylor as trade secrets, and was not known to either the public or the industries in which it might be exploited.

### **LICENSING THE ELLEDGE TECHNOLOGY**

9. In April of 1998, Baylor entered into licensing negotiations with Clontech over the Elledge technology. As part of those negotiations, it was necessary for Baylor to transfer various trade secrets, information, and material to Clontech. Before this was done, Clontech signed a Confidential Disclosure Agreement with BCMT and a Material Transfer Agreement with Baylor. Subsequent to these two contracts, Baylor disclosed the Elledge technology to Clontech including the then pending patent application covering part of the technology, and allowed them free communication with Dr. Elledge. Approximately two weeks after the agreements were signed the Elledge technology materials were sent to Clontech including:

- (1) a uni-vector plasmid (pUNI10);
- (2) a recipient plasmid (e.g.: pHB2-Gst, a bacterial Gst fusion plasmid with a lox site);
- (3) a recombinase expression plasmid (e.g.: pQLI23, the Gst-cre expression plasmid); and
- (4) the cell lines for conducting the studies (BUN13 and BUN15)

The listed information and materials, together with all other information and materials furnished to Clontech shall hereafter be referred to as the "*Elledge trade secrets*".

10. Under the terms of the Confidential Disclosure Agreement and Material Transfer Agreement, Clontech agreed not to disclose any of the Elledge trade secrets, including the



Elledge technology, unless such information became publicly available, and to use the materials only to evaluate the technology. Clontech also agreed that all rights to any technology developed via use of the Elledge trade secrets belonged to Baylor. Specific key provisions of the Confidential Disclosure Agreement include:

- (1) Clontech may only use the confidential information for the "sole purpose of evaluating the scientific and technical merit and commercial potential thereof." [¶ 1]
- (2) Clontech acknowledges BCMT is providing them "trade secrets, know-how and confidential data or materials." [*Id.*]
- (3) Certain Clontech obligations under the agreement cease if the information becomes public through no fault of Clontech. [¶ 3(a)]
- (4) If there is a breach, "the damage will be substantial, although difficult to quantify, and money damages will not afford an adequate remedy. Therefore . . . BCMT shall have the right to . . .[a] temporary or permanent injunction." [¶ 6]

11. Key provisions of the Material Transfer Agreement include:

- (1) the research material "will only be used [by Clontech] for non-commercial evaluation of the Research Material . . . and [to] determine suitability for potential license arrangement. Any and all other studies or uses are expressly prohibited and may not be pursued by the Recipient . . . . *The Research Materials will not be used for commercial purposes . . . .*" [¶ 2] (emphasis added).
- (2) "When the Research Project" is completed . . . Recipient will destroy the Research Material and advise BCM of such destruction." [¶ 5]
- (3) "BCM hereby retains and Recipient hereby grants BCM all rights in and to all inventions made through the use of the Research Material. Recipient agrees that it will promptly disclose to BCM all inventions made through the use of the Research Material and will assign such rights to BCM, subject to the right of the Recipient to a non-exclusive license to use the same for research purposes." [¶ 6]

12. Between July 1998 and December 1998, Clontech and Baylor attempted without success to negotiate terms for a license to the Elledge technology.

13. On December 17, 1998 Baylor advised Clontech that the technology would be licensed to a different company.

## DEFENDANT CLONTECH

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## COUNT I - BREACH OF CONTRACT

17. For this cause of action, Baylor and BCMT repeat and adopt all allegations contained in paragraphs 1 through 16 above.

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23. Baylor and BCMT are, and at all times mentioned in this petition have been, engaged in an effort to develop and commercialize the technology at issue in this litigation.

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32. Baylor and BCMT demand a jury trial as to all matters in this action, whether currently pleaded or as may be later pleaded, to which it may be entitled under the Constitution, laws, or statutes of the United States, or any applicable state constitution, law, or statute, or at common law.

#### **PRAYER FOR RELIEF**

Wherefore, Baylor and BCMT pray for relief as follows:

(1) Injunctive Relief

Granting a permanent injunction against defendant, its agents, representatives, employees and servants and all persons and entities in concert or participation with it, and

- a. ordering it to immediately turn over to plaintiffs (i) all Elledge trade secrets and derived information in whatever form (including all documents, records, laboratory notebooks, computer disks, files, correspondence, mail, and other materials), and (ii) the Creator system and derived information in whatever form (including all documents, records, laboratory notebooks, computer disks, files, correspondence, mail, and other materials);

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- c. ordering that Clontech cease and refrain from engaging in any conduct or activity which has the effect of interfering with terminating or diminishing any of plaintiffs' contracts and/or business relationships with prospective licensees; and
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(2) Actual damages in an amount to be determined at trial.

(3) Punitive damages in an amount of at least three times the amount of actual damages awarded;

(4) An equitable order requiring defendant to disgorge to plaintiffs the full amount of all royalties, licensing fees, sales, and profits it has collected or retained in connection with (i) the Elledge trade secrets and any derived information or technology and (ii) the Creator system and any derived information or technology;

(5) An assignment of all right and interest over all data, work product, intellectual property (including, but not limited to all patents and patent applications), personal property, trade secrets which are related to the Elledge trade secrets, the Creator system, or any derived information or technology.

(6) Reasonable and necessary attorneys' fees incurred by plaintiffs in connection with this action, pursuant to Chapter 38 of the Texas Civil Practice & Remedies Code and other applicable law;

(7) Prejudgment and post-judgment interest at the highest rate(s) allowed by law;

(8) Costs of court; and

(9) Such other and further relief that this Court may deem just and proper.

Respectfully submitted,



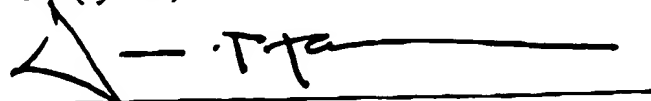
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*Attorneys for Plaintiffs  
Baylor College of Medicine and  
BCM Technologies, Inc.*

### CERTIFICATE OF SERVICE

I certify that on May 3, 2002, a true and correct copy of the foregoing was served on (i) Glenn A. Ballard, Jr. of Bracewell & Patterson LLP, 711 Louisiana St., Suite 2900, Houston, Texas 77002-2781 (*by Fax*); (ii) Richard J. Oparil of Patton Boggs LLP, 2550 M Street, NW, Washington, DC 20037 (*by Fax*) and (iii) Marc R. Labgold, Ph.D. of Patton Boggs LLP, 8484 West Park Drive, Suite 900, McClean, VA 22102 (*by Fax*).

  
\_\_\_\_\_  
David P. Blanke

**Michael M. Stry, Clerk**

~~~~~

**Civil Action No.** \_\_\_\_\_



### **The Parties**

2. Plaintiff Clontech Laboratories, Inc. ("Clontech") is a corporation organized under the laws of the state of Delaware and having its principal place of business at 1020 East Meadow Circle, Palo Alto, California, 94303.

3. On information and belief, Defendant BCM Technologies, Inc. is a corporation organized under the laws of the state of Delaware and having its principal place of business at 1709 Dryden Road, Suite 900, Houston, Texas 77030 ("BCMT").

4. On information and belief, Defendant Baylor College of Medicine is a nonprofit corporation organized and existing under the laws of the State of Texas and having a principal place of business at One Baylor Plaza, Houston, Texas 77030 ("Baylor").

### **Venue and Personal Jurisdiction**

5. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b)-(c). Defendant Baylor, a Texas nonprofit corporation and Defendant BCMT, a corporation having its principal place of business in Houston, Texas, have accused Plaintiff of using its patented technology and threatened to sue Plaintiff, a Delaware corporation doing business in the State of Texas, for patent infringement. Venue for such a suit is proper in this district and in Texas given that both corporate Defendants reside therein.

### **The Patent-in-Suit**

6. On information and belief, Baylor is the assignee of United States Patent No. 5,851,808 to Stephen J. Elledge and Qinghua Liu, entitled RAPID SUBCLONING USING SITE-SPECIFIC RECOMBINATION, and which issued on December 22, 1998 ("the '808 patent"). (A copy of the '808 patent is appended hereto as Exhibit A).

### **Case or Controversy**

7. An immediate, real, and justiciable controversy exists between the parties to this action. As set forth in paragraphs 8-19 below, Baylor and BCMT have threatened Clontech in a manner which has caused Clontech to have a reasonable apprehension that the Defendants will sue Clontech for the alleged infringement of the '808 patent through its past offerings for sale and continuing sales of its Creator™ products and products which depend upon or include the Creator™ technology.

8. In April of 1998, Plaintiff Clontech entered into licensing negotiations with Baylor with respect to certain technology covered by the '808 patent ("the Elledge technology"). As part of those negotiations, it was necessary for Clontech to receive various materials and information from Baylor and BCMT.

9. Clontech agreed to use any information and/or materials it received from BCMT for purposes of evaluating its possible scientific and technical merits and its possible commercial potential.

10. Between July 1998 and December 1998, Clontech and Baylor unsuccessfully attempted to negotiate terms for a license to the technology covered by the '808 patent.

11. On December 17, 1998, Baylor informed Clontech that the technology covered by the '808 patent would be licensed to another company and not to Clontech. (The '808 patent then issued on December 22, 1998).

12. Clontech, upon receiving notice from Baylor that they would not be granted a license to the '808 patent's technology, continued its prior efforts towards the independent development of its own proprietary rapid subcloning technology. These efforts resulted in the development of a novel methodology which Clontech commercialized as its Creator™ products and technology. Clontech's developmental efforts did not incorporate or otherwise include any information or materials received from Baylor and/or BCMT.

13. In 1999, as a result of its independent development efforts, Clontech commercially launched its Creator™ system for rapid subcloning of DNA. Clontech has also filed a U.S. Patent Application directed to this proprietary version of rapid subcloning technology. Clontech's developmental work and the achievement of the novel and proprietary Creator™ product(s) was accomplished independently of any information or materials received from Baylor and/or BCMT.

14. On or about December 5, 2001, Baylor and BCMT filed a Texas state court action in the 133<sup>rd</sup> Judicial District Court of Harris County, Texas, Cause No. 2001-61352 ("the State Action"), against Clontech for various causes of action which are factually and legally intertwined with the allegations of this Complaint. The State Action allegations include breach of contract, misappropriation of trade secrets, statutory theft of trade secrets, breach of fiduciary relationship and conversion. (A copy of the Petition is attached hereto as Exhibit B).

15. In the State Action, Baylor has alleged that certain biological materials, including specific plasmids and cell lines (which Baylor defined therein as the “Elledge trade secrets”), were employed by Clontech in the development of Clontech’s Creator™ technology.

16. Baylor and BCMT have specifically alleged that: “Clontech’s Creator system is based upon and makes use of the Elledge trade secrets, including Elledge technology, and will continue to use the trade secrets, including the Elledge technology, thereby causing irreparable harm to Baylor and BCMT.” (Exhibit B at ¶ 16).

17. Baylor and BCMT have alleged the Elledge technology is covered by the ’808 patent and that Clontech has made use of and continues to use the Elledge technology. As such, Baylor and BCMT have accused Clontech of infringing the ’808 patent.

18. In its Prayer for Relief in the State Action, Baylor and BCMT seek several forms of relief which are normally available under the federal patent laws of Title 35 of the United States Code and the applicable Federal Circuit precedent. Such forms of relief include injunction, attorneys’ fees, and actual and treble damages as specified in the federal patent laws at 35 U.S.C. §§ 283-285. (*Cf.* Exhibit B at pp. 9-11).

19. Further, representatives of Baylor have publicly stated that Baylor intends to sue Clontech for infringement of the ’808 patent.

20. As demonstrated in the foregoing paragraphs, Clontech has a reasonable apprehension that, as demonstrated by and in addition to the State Action, it will be sued for patent infringement by Baylor and BCMT based upon its marketing and sales of its proprietary Creator™ products. Hence, an immediate, real, and justiciable controversy exists between the parties which gives rise to this declaratory judgment action.

### **Allegation of Non-Infringement**

21. Clontech incorporates by reference the specific allegations of paragraphs 1-20.

22. Clontech has not infringed, and does not infringe, any valid claim of the '808 patent.

23. Clontech neither used the Elledge information or materials in its Creator™ technology nor did it base its Creator™ technology on any materials or information it received from Baylor or BCMT.

24. The development of Clontech's Creator™ technology was entirely independent of Clontech's interaction with Baylor and without any benefit of the Elledge information, technology or materials, and the Creator™ products do not fall within the scope of any of the '808 patent claims.

### **Allegation of Invalidity**

25. Clontech incorporates by reference the specific allegations of paragraphs 1-24.

26. On information and belief, the claims of the '808 patent are invalid under the patent laws of the United States, as codified in Title 35 of the United States Code including, but not limited to, §§ 102, 103 and 112.

27. On information and belief, the claims of the '808 patent are invalid under 35 U.S.C. § 112, ¶ 1 for, *inter alia*, failure to comply with the best mode requirement. Baylor and BCMT have admitted that it maintains information concerning the Elledge technology as a trade secret thereby violating its obligations under 35 U.S.C. § 112, ¶ 1.

28. On information and belief, the claims of the '808 patent are invalid as anticipated, derived from and/or obvious under 35 U.S.C. § 102/103 over the prior art.

**Request for Relief**

29. Clontech respectfully requests:

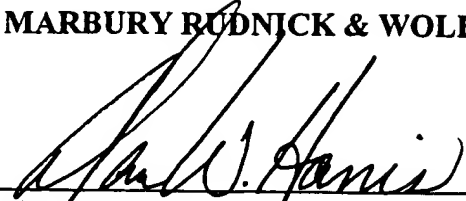
- a. a judgment declaring that Plaintiff has not infringed, and is not presently infringing, the '808 patent;
- b. a judgment declaring that the claims of the '808 patent are invalid;
- c. a judgment awarding its attorney fees pursuant to 35 U.S.C. § 285;
- d. a judgment awarding its costs (Fed. R. Civ. P. 54(d)); and
- e. any other relief the Court may deem appropriate under the circumstances.

Dated: January 4, 2002.

Respectfully submitted,

**PIPER MARBURY RUDNICK & WOLFE LLP**

By: \_\_\_\_\_

  
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**ATTORNEYS FOR DEFENDANT  
CLONTECH LABORATORIES, INC.**

2001-61352

CAUSE NO. \_\_\_\_\_

|                             |
|-----------------------------|
| ASSESSED                    |
| ENTERED <i>[Signature]</i>  |
| VERIFIED <i>[Signature]</i> |

BAYLOR COLLEGE OF MEDICINE and  
BCM TECHNOLOGIES, INC.,

*Plaintiffs,*

v.

CLONTECH LABS, INC.,

*Defendant.*

IN THE DISTRICT COURT

HARRIS COUNTY, TEXAS

33 JUDICIAL DISTRICT

### PLAINTIFFS' ORIGINAL PETITION

Plaintiffs Baylor College of Medicine ("*Baylor*") and BCM Technologies, Inc. ("*BCMT*") complain of defendant Clontech Labs, Inc. ("*Clontech*") as follows:

### PARTIES

1. Plaintiff Baylor is a nonprofit corporation organized and existing under the laws of the State of Texas having a principal place of business at Baylor Plaza, Houston, Texas 77030. Plaintiff BCMT is a Delaware corporation that maintains its principal place of business at 1709 Dryden Road, Suite 900, Houston, Texas 77030. BCMT is a wholly-owned subsidiary of Baylor responsible for licensing Baylor's technology.
2. Defendant Clontech is a Delaware corporation having its principal place of business at 1020 E. Meadow Circle, Palo Alto, California 94303. Because Clontech has not designated a registered agent for service of process in Texas, pursuant to § 17.044 of the Texas Civil Practice & Remedies Code, service may be effectuated by serving the Texas Secretary of State with the complaint, who shall then immediately mail a copy thereof to Clontech at its principal place of business.



## JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction in that more than the minimum jurisdictional amount is in controversy. Personal jurisdiction is proper as defendant Clontech is doing business within Texas, purposely directed tortious activity at Texas that caused harm in Texas, and entered into a contract with Texas residents requiring performance in whole or in part in this State.

4. Venue is proper in that this action centers on (i) contracts that were entered into in Harris County, Texas, which were performable, at least in part, in the County and (ii) torts that were committed, in whole or in part, in Harris County, Texas.

## PLAINTIFF BAYLOR

5. Baylor College of Medicine has earned a reputation as one of the leading medical universities. Baylor attracts students from around the world and is home to 668 medical students, 399 graduate students, 255 postdoctoral fellows, 125 allied health students, and 962 resident physicians pursuing specialty training. In conjunction with its training and schooling, Baylor offers patient care services through several of its Texas Medical Center affiliate hospitals, providing more than 131,000 inpatient visits and nearly 2 million outpatient visits annually.

6. In the past fiscal year, Baylor was ranked number one among universities and colleges in total and federally financed research and development expenditures in the biological sciences and thirteenth in National Institute of Health funding to medical schools. The college, with total research support of \$310 million, has more than 70 research and patient-care centers.

centers. The only private medical school in the Greater Southwest, Baylor is among the top 20 of the 125 U.S. medical schools in federal research funding.

7. Over the years, Baylor has expended considerable sums of money on research and development in subcloning of nucleic acid sequences at its Houston facilities in an effort to discover, improve and commercialize products related to identifying the functions of genes. As a result of its development efforts in the field of genomic research, Steve Elledge developed novel compositions and methods for rapid subcloning of DNA which provided a very quick and simple system of identifying genes ("*the Elledge technology*"). In 1997 Baylor applied for a patent covering some of the Elledge technology. The patent was assigned to Baylor and ultimately issued December 22, 1998 as U.S. Patent 5,851,808 ("*the '808 patent*").

8. Just prior to the '808 patent issuing, Elledge published an article disclosing some of the Elledge technology on November 19, 1998. Prior to this publication, the Elledge technology was kept confidential by Baylor as trade secrets, and was not known to either the public or the industries in which it might be exploited.

### LICENSING THE ELLEDGE TECHNOLOGY

9. In April of 1998, Baylor entered into licensing negotiations with Clontech over the Elledge technology. As part of those negotiations, it was necessary for Baylor to transfer various trade secrets, information, and material to Clontech. Before this was done, Clontech signed a Confidential Disclosure Agreement with BCMT and a Material Transfer Agreement with Baylor. Subsequent to these two contracts, Baylor disclosed the Elledge technology to Clontech including the then pending patent application covering part of the technology, and

allowed them free communication with Dr. Elledge. Approximately two weeks after the agreements were signed the Elledge technology materials were sent to Clontech including:

- (1) a uni-vector plasmid (pUNI10);
- (2) a recipient plasmid (e.g.: pHB2-Gst, a bacterial Gst fusion plasmid with a lox site);
- (3) a recombinase expression plasmid (e.g.: pQLI23, the Gst-cre expression plasmid); and
- (4) the cell lines for conducting the studies (BUN13 and BUN15)

The listed information and materials, together with all other information and materials furnished to Clontech shall hereafter be referred to as the "*Elledge trade secrets*".

10. Under the terms of the Confidential Disclosure Agreement and Material Transfer Agreement, Clontech agreed not to disclose any of the Elledge trade secrets, including the Elledge technology, unless such information became publicly available, and to use the materials only to evaluate the technology. Clontech also agreed that all rights to any technology developed via use of the Elledge trade secrets belonged to Baylor. Specific key provisions of the Confidential Disclosure Agreement include:

- (1) Clontech may only use the confidential information for the "sole purpose of evaluating the scientific and technical merit and commercial potential thereof." [¶ 1]
- (2) Clontech acknowledges BCMT is providing them "trade secrets, know-how and confidential data or materials." [Id.]
- (3) Certain Clontech obligations under the agreement cease if the information becomes public through no fault of Clontech. [¶ 3(a)]
- (4) If there is a breach, "the damage will be substantial, although difficult to quantify, and money damages will not afford an adequate remedy. Therefore . . . BCMT shall have the right to . . . [a] temporary or permanent injunction." [¶ 6]

11. Key provisions of the Material Transfer Agreement include:

- (1) the research material "will only be used [by Clontech] for non-commercial evaluation of the Research Material . . . and [to] determine suitability for potential license arrangement. Any and all other studies or uses are expressly prohibited and may not be pursued by the Recipient . . . . *The Research Materials will not be used for commercial purposes . . . .*" [¶ 2] (emphasis added).
- (2) "When the Research Project" is completed . . . Recipient will destroy the Research Material and advise BCM of such destruction." [¶ 5]
- (3) "BCM hereby retains and Recipient hereby grants BCM all rights in and to all inventions made through the use of the Research Material. Recipient agrees that it will promptly disclose to BCM all inventions made through the use of the Research Material and will assign such rights to BCM, subject to the right of the Recipient to a non-exclusive license to use the same for research purposes." [¶ 6]

12. Between July 1998 and December 1998, Clontech and Baylor attempted without success to negotiate terms for a license to the Elledge technology.

13. On December 17, 1998 Baylor advised Clontech that the technology would be licensed to a different company.

#### DEFENDANT CLONTECH

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25. Clontech intentionally and wrongfully misappropriated trade secrets from Baylor and BCMT for the purpose of commercially using them.

## **COUNT III - CONVERSION**

26. Paragraphs 1 through 25 are specifically incorporated into this cause of action.

27. Clontech has unlawfully asserted dominion and control over property owned by Baylor and BCMT by:

- a. gaining access to Baylor and BCMT's confidential and trade secret information and materials; and

- b. taking Baylor and BCMT's confidential information, trade secrets, and materials and converting them for its own use.

28. Upon information and belief the conversion by Clontech has been willful and malicious, with an attempt to cause the harm alleged.

#### **COUNT IV - BREACH OF FIDUCIARY RELATIONSHIP**

29. Paragraphs 1 through 28 are specifically incorporated in this cause of action.

30. Clontech undertook a relationship of trust and confidence with Baylor and BCMT whereby Clontech owed Baylor and BCMT fiduciary duties, including duties of good faith and fair dealing, loyalty, and full disclosure to Baylor and BCMT.

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34. Pursuant to § 134.003 of Texas Civil Practice & Remedies Code, and § 31.05 of the Texas Penal Code, Clontech should be held liable for theft of trade secrets. Pursuant to § 134.005(b) of Texas Civil Practice & Remedies Code, plaintiffs are also entitled to attorneys' fees and costs.

### **JURY DEMAND**

35. Baylor and BCMT demand a jury trial as to all matters in this action, whether currently pleaded or as may be later pleaded, to which it may be entitled under the Constitution, laws, or statutes of the United States, or any applicable state constitution, law, or statute, or at common law.

### **PRAYER FOR RELIEF**

Wherefore, Baylor and BCMT pray for relief as follows:

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Granting a permanent injunction against defendant, its agents, representatives, employees and servants and all persons and entities in concert or participation with it, and

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- c. ordering that Clontech cease and refrain from engaging in any conduct or activity which has the effect of interfering with terminating or diminishing any of plaintiffs' contracts and/or business relationships with prospective licensees; and
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- (5) An assignment of all right and interest over all data, work product, intellectual property (including, but not limited to all patents and patent applications), personal property, trade secrets which are related to the Elledge trade secrets, the Creator system, or any derived information or technology.

(6) Reasonable and necessary attorneys' fees incurred by plaintiffs in connection with this action, pursuant to Chapter 38 of the Texas Civil Practice & Remedies Code and other applicable law;

(7) Prejudgment and post-judgment interest at the highest rate(s) allowed by law;

(8) Costs of court; and

(9) Such other and further relief that this Court may deem just and proper.

Respectfully submitted,

VINSON & ELKINS L.L.P.

  
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Tracey Davies

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*Attorneys for Plaintiffs*

*Baylor College of Medicine  
and BCM Technologies, Inc.*

34-  
IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF TEXAS  
HOUSTON DIVISION

UNITED STATES COURTS  
SOUTHERN DISTRICT OF TEXAS  
ENTERED

APR - 7 2003

CLONTECH LABORATORIES, INC.,

*Plaintiff,*

v.

BAYLOR COLLEGE OF MEDICINE and  
BCM TECHNOLOGIES, INC.,

*Defendants.*

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§

Civil Action No. H02-0017

Michael N. Meby, Clerk of Court

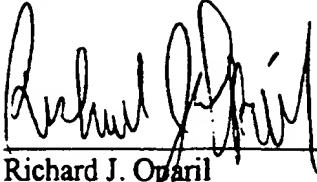
**STIPULATION AND ORDER OF DISMISSAL**

The defendants, Baylor College of Medicine and BCM Technologies, Inc., and non-party Invitrogen Corporation, having covenanted not to assert the disputed patent against plaintiff Clontech Laboratories, Inc., according to the terms set forth in Exhibit A, and the parties hereby stipulating to dismissal, this action is dismissed pursuant to Fed. R. Civ. P. 41(a)(1)(ii), with all costs taxed against the party incurring same.

So ordered this 7<sup>th</sup> day of ~~March~~ <sup>April</sup>, 2003.

  
United States District Judge

**AGREED:**



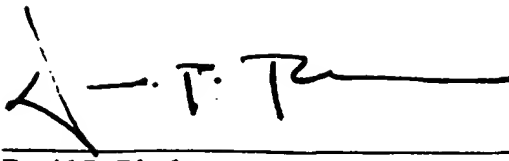
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#3672159



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*Attorneys for Defendants  
Baylor College of Medicine and  
BCM Technologies, Inc.*

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF TEXAS  
HOUSTON DIVISION

CLONTECH LABORATORIES, INC.,

Plaintiff,

v.

BAYLOR COLLEGE OF MEDICINE and  
BCM TECHNOLOGIES, INC.,

Defendants.

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Civil Action No. H02-0017

**COVENANT NOT TO ASSERT U.S. PATENT NO. 5,851,808  
AGAINST CLONTECH LABORATORIES, INC.**

Whereas, defendant Baylor College of Medicine is the assignee of U.S. Patent No. 5,851,808 (the "'808 Patent").

Whereas, Invitrogen Corporation ("Invitrogen") is the exclusive licensee of the '808 patent.

Whereas, this declaratory judgment action relating to the '808 Patent, filed on January 4, 2002, by plaintiff, Clontech Laboratories, Inc. ("Clontech"), against the defendants, Baylor College of Medicine and BCM Technologies, Inc. (collectively "Baylor") sought a declaratory judgment that Clontech did not infringe the '808 Patent and/or that the '808 Patent was invalid (Docket No. 1).

Whereas, Baylor moved to dismiss the complaint under Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction on the ground that there was no case or controversy between the parties (Docket No. 12).

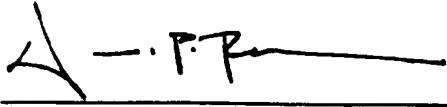
**EXHIBIT A**

Whereas, on February 6, 2003, this Court denied that motion, finding, *inter alia*, that Baylor has not assured either this Court or Clontech that it will not bring an infringement suit against Clontech (Docket No. 31).

Now, therefore, Baylor and Invitrogen hereby covenant not to assert the '808 Patent against Clontech with respect to its past Creator™ products, and existing Creator™ products as of the date of this covenant. This covenant is without prejudice to Baylor and Invitrogen's right to assert the '808 Patent against other parties. This covenant also is without prejudice to any other patents, including continuations, continuations-in-part, divisionals, reissue, and reexamined patents, as well as foreign counterparts.

Dated this 20th day of March, 2003.

AGREED:



---

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M. Michelle Muller  
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Attorneys for Defendants Baylor College of  
Medicine and BCM Technologies, Inc. and  
Non-Party Invitrogen Corporation

#3672156

Notice: The attached order has been entered.



Kevin M Bell 4:02-cv-00017 35 aty  
Patton Boggs LLP  
8484 Westpark Dr  
Ste 900  
McLean, VA 22012

-----  
4:02-cv-00017 #35  
5 page(s).  
04/07/03  
-----

AUTHORIZATION TO SEND NOTICES  
BY FACSIMILE

In all cases where I appear as an attorney, the Clerk of the United States District Court for the Southern District of Texas may send me notices by facsimile transmission rather than mail.  
See Fed.R.Civ.P. 77, Fed.R.Crim.P. 49, Fed.R.Bankr.P. 9022,9036.

This telephone line is dedicated for facsimile transmission:

Fax: ( ) \_\_\_\_\_

Name: \_\_\_\_\_ State Bar Number: \_\_\_\_\_

Signature: \_\_\_\_\_

Complete ONLY information that is different from the address listed above.

Firm: \_\_\_\_\_

Suite: \_\_\_\_\_

Street or P. O. Box: \_\_\_\_\_

City, State and Zip: \_\_\_\_\_

Business Telephone: ( ) \_\_\_\_\_

Mail to: Attorney Admissions  
United States District Clerk  
P. O. Box 61010  
Houston, TX 77208

Control: CV-INS\_image5-9124



February 17, 2003

***By Overnight Delivery***

Michael N. Milby  
United States District Court  
Southern District of Texas  
515 Rusk Avenue  
Houston, Texas 77002

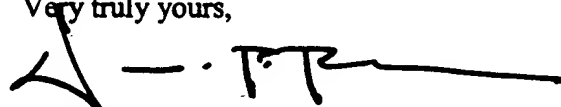
Re: *Clontech Laboratories, Inc. v. Baylor College of Medicine, et al.*;  
United States District Court for the Southern District of Texas, Houston Division;  
Civil Action No. 4-02-0017

Dear Mr. Milby:

Enclosed for filing with the papers of the above referenced case are an original and one copy of Baylor's second motion to dismiss with accompanying covenant not to assert. Also enclosed is an extra copy, which we ask that you file mark and return in the enclosed self-addressed, stamped envelope.

Thank you for your assistance in this regard.

Very truly yours,



David P. Blanke

c: Glenn A. Ballard, Jr.  
Richard J. Oparil  
Kevin Bell  
*(all w/encls.; by fax and first class mail)*

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF TEXAS  
HOUSTON DIVISION

CLONTECH LABORATORIES, INC.,

*Plaintiff,*

v.

BAYLOR COLLEGE OF MEDICINE and  
BMC TECHNOLOGIES, INC.,

*Defendants.*

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§

Civil Action No. H02-0017

**BAYLOR'S SECOND MOTION TO DISMISS  
WITH ACCOMPANYING COVENANT NOT TO ASSERT**

Defendants BCM Technologies, Inc. and Baylor College of Medicine (collectively, "*Baylor*") file this second motion to dismiss, with an accompanying covenant not to assert the disputed patent, respectfully submitting that this case should be dismissed for want of subject matter jurisdiction.

**I.**

This declaratory judgment action seeks to invalidate United States Patent No. 5,851,808 (the "*Disputed Patent*"), which was issued to Drs. Stephen J. Elledge and Qinghua Liu on December 22, 1998, and assigned to Baylor. Last year, Baylor moved to dismiss this case, arguing that there is no case or controversy regarding the Disputed Patent between Baylor and Clontech Laboratories, Inc. ("*Clontech*"). Recently, the Court denied that motion. "Based on the totality of the circumstances," the Court concluded that "an actual case of controversy exists with respect to the [Disputed Patent]." Memorandum & Order, entered February 6, 2003, at pp. 12-13.

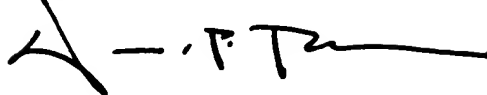
## II.

As Clontech recognized in its papers opposing Baylor's motion, "Baylor itself can control the disposition of this action." Plaintiff's Opposition to Defendants' Motion to Dismiss, filed March 25, 2002, at p. 14. "[A] patentee defending an action for declaratory judgment of invalidity can divest the trial court of jurisdiction over the case by filing a covenant not to assert the patent at issue against the putative infringer with respect to any of its past, present, or future acts." *Id.* (quoting *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058 (Fed. Cir. 1995), *cert. denied*, 516 U.S. 1093 (1996)). Baylor's initial motion to dismiss did not include such a covenant.

## III.

With this second motion to dismiss, Baylor submits a covenant not to assert the Disputed Patent. See Exhibit A. That covenant "divest[s] the trial court of jurisdiction over the case." *Super Sack Mfg. Corp.*, 57 F.3d at 1058. For that reason, Baylor respectfully submits the Court should dismiss this case for want to subject matter jurisdiction.

Respectfully submitted,



---

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State Bar No. 24001858  
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(713) 758-2346 (Fax)

*Attorneys for Defendants Baylor College of  
Medicine and BCM Technologies, Inc.*

## CERTIFICATE OF SERVICE

I certify that on February 17, 2003, a true and correct copy of the foregoing was served on (i) Glenn A. Ballard, Jr. of Bracewell & Patterson LLP, 711 Louisiana St., Suite 2900, Houston, TX 77002-2781 (*by fax and first class mail*); (ii) Richard J. Oparil of Patton Boggs LLP, 2550 M Street, NW, Washington, DC 20037 (*by fax and first class mail*) and (iii) Marc R. Labgold and Kevin M. Bell of Patton Boggs LLP, 8484 Westpark Drive, Suite 900, McLean, VA 22102 (*by fax and first class mail*).

A handwritten signature in black ink, appearing to read "D. P. Blanke", written over a horizontal line.

David P. Blanke

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF TEXAS  
HOUSTON DIVISION

|                                |   |                           |
|--------------------------------|---|---------------------------|
| CLONTECH LABORATORIES, INC.,   | § |                           |
|                                | § |                           |
| <i>Plaintiff,</i>              | § |                           |
|                                | § | Civil Action No. H02-0017 |
| v.                             | § |                           |
|                                | § |                           |
| BAYLOR COLLEGE OF MEDICINE and | § |                           |
| BCM TECHNOLOGIES, INC.,        | § |                           |
|                                | § |                           |
| <i>Defendants.</i>             | § |                           |

**BAYLOR'S COVENANT NOT TO ASSERT THE '808 PATENT**

Whereas, Baylor College of Medicine and BMC Technologies, Inc. (collectively, "*Baylor*") filed suit against Clontech Laboratories, Inc. ("*Clontech*") on November 30, 2001, which suit is styled *Baylor College of Medicine and BCM Technologies, Inc. v. Clontech Labs, Inc.*, numbered 2001-61352, and assigned to the 133rd Judicial District Court for Harris County, Texas (the "*State Court Suit*").

Whereas, in the State Court Suit Baylor alleged solely state law causes of action arising out of Clontech's misappropriation of technology and trade secret materials Baylor had furnished to Clontech.

Whereas, on January 4, 2002, Clontech (i) removed the State Court Suit to Federal Court, alleging that Baylor's state law claims necessarily hinged on a substantial question of patent law relating to U.S. Patent 5,851,808 (the "'808 Patent") obtained by Baylor, and (ii) simultaneously filed this declaratory judgment action, feigning apprehension of a infringement suit by Baylor under the '808 Patent.

**EXHIBIT A**

Whereas, the Federal Court to which the State Court Suit was removed remanded the State Court Suit after "conclud[ing] that Clontech did not have an objectively reasonable basis upon which to believe that removal was proper." Memorandum Opinion and Order at p. 8.

Whereas, Baylor has moved to dismiss this declaratory judgment action, pointing out that, *inter alia*, this suit is a procedural ploy on Clontech's part to litigate its defense to the State Court Suit in Federal Court, which ploy is apparent on the face of Clontech's pleading. See Complaint for Declaratory Judgment at ¶¶ 23 & ¶ 24.

Whereas, Clontech has filed its opposition to Baylor's motion to dismiss, reiterating its mock-fear of an infringement suit based on the '808 Patent.

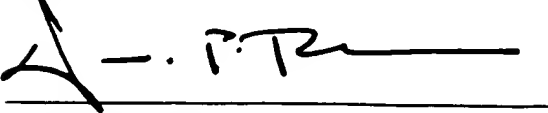
Whereas, Clontech, however, acknowledges that "Baylor itself can control the disposition of this action" because a "patentee defending against an action for declaratory judgment of invalidity can divest the trial court of jurisdiction over the case by filing a covenant not to assert the patent at issue against the putative infringer with respect to its past, present, or future acts." Plaintiff's Opposition to Defendant's Motion to Dismiss at p. 14 (quoting *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058 (Fed. Cir. 1995), *cert. denied*, 516 U.S. 1093 (1996)).

Now, Therefore, to avoid the entirely unnecessary and unprincipled tax on this Court's energies and resources that Clontech seeks to impose, and to move forward with the State Court Suit unburdened by Clontech's jurisdictional machinations, Baylor hereby covenants not to assert the '808 Patent against Clontech with respect to its existing or past Creator™ products, as of the date of this covenant. This covenant is without prejudice to Baylor's right to assert the '808 Patent against other parties. This covenant also is without prejudice to any other patents,

including continuations, continuations-in-part, divisionals, reissue, and reexamined patents, as well as foreign counterparts.

Dated this 17th day of February, 2003.

**AGREED:**

A handwritten signature in black ink, appearing to read 'D. P. Blanke', is written over a horizontal line.

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Tracey Davies  
State Bar No. 24001858  
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*Attorneys for Defendants Baylor College of  
Medicine and BCM Technologies, Inc.*



---

**ORAL DEPOSITION OF QINGHUA LIU**

**February 7, 2003**

---



CONDENSED TRANSCRIPT AND CONCORDANCE  
PREPARED BY:

**Sunbelt Reporting & Litigation Services**  
**(713) 667-0763 Houston**  
**(214) 747-0763 Dallas**

## Page 1

1 CAUSE NO. 2001-61352  
 2 BAYLOR COLLEGE OF MEDICINE ) IN THE DISTRICT COURT OF  
 3 and BCM TECHNOLOGIES, INC., )  
 4 )  
 5 Plaintiffs/Counter-defendants.)  
 6 )  
 7 VS. )  
 8 )  
 9 CLONTECH LABORATORIES, INC., ) HARRIS COUNTY, T E X A S  
 10 )  
 11 Defendant/Counter-plaintiff. )  
 12 )  
 13 VS. )  
 14 )  
 15 INVITROGEN CORPORATION, )  
 16 )  
 17 Additional Counterclaim )  
 18 Defendant. ) 133RD JUDICIAL DISTRICT  
 19 \*\*\*\*\*  
 20 ORAL DEPOSITION OF  
 21 QINGHUA LIU  
 22 February 7, 2003  
 23 \*\*\*\*\*  
 24 Reported By: Taye J. Clark  
 25 Job No. 39664

## Page 3

1 ORAL DEPOSITION OF  
 2 QINGHUA LIU, produced as a witness at the instance of  
 3 the DEFENDANT/COUNTER-PLAINTIFF, and duly sworn, was  
 4 taken in the above-styled and numbered cause on the 7th  
 5 day of February, from 9:14 a.m. to 10:58 a.m., before  
 6 Taye J. Clark, CSR in and for the State of Texas,  
 7 reported at the offices of Patton Boggs, LLP, 2001 Ross  
 8 Avenue, Suite 3000, Dallas, Texas 75201, pursuant to  
 9 the Texas Rules of Civil Procedure and the provisions  
 10 stated on the record or attached hereto.  
 11

## A P P E A R A N C E S

## FOR THE PLAINTIFFS/COUNTER-DEFENDANTS:

14 MS. M. MICHELLE MULLER, PH.D.  
 15 Vinson & Elkins  
 The Terrace 7  
 16 2801 Via Fortuna, Suite 100  
 Austin, Texas 78746-7568  
 17

## FOR THE DEFENDANT/COUNTER-PLAINTIFF:

18 MR. MARC R. LABGOLD, PH.D.  
 19 Patton Boggs, LLP  
 20 8484 Westpark Drive  
 McLean, Virginia 22102  
 21  
 22  
 23  
 24  
 25

## Page 2

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| 4  | Preliminary Proceedings                                                                                | 4    |
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| 7  | Further Examination by Mr. Marc R. Labgold                                                             | 60   |
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| 12 | EXHIBIT INDEX                                                                                          |      |
| 13 |                                                                                                        |      |
| 14 | NUMBER DESCRIPTION PAGE MARKED                                                                         |      |
| 15 | 1 BCMT Technologies, Inc., memorandum dated March 18, 1999 to James S. Friou from Christine B. Powaser | 10   |
| 16 |                                                                                                        |      |
| 17 | 2 Affidavit of Qinghua Liu, Ph.D.                                                                      | 13   |
| 18 | 3 United States Patent No. 005851808A                                                                  | 18   |
| 19 | 4 Handwritten notes                                                                                    | 53   |
| 20 | 5 Handwritten notes                                                                                    | 53   |
| 21 | 6 Copy of an e-mail from "Qun Shan" to "mamie" dated Monday, August 17th, 1998                         | 60   |
| 22 |                                                                                                        |      |
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| 24 |                                                                                                        |      |
| 25 |                                                                                                        |      |

## Page 4

1 PRELIMINARY PROCEEDINGS  
 2 THE REPORTER: Going on the record at  
 3 9:14 a.m.  
 4 QINGHUA LIU,  
 5 having been first duly sworn, testified as follows:  
 6 THE REPORTER: By the Rules?  
 7 MR. LABGOLD: Yes.  
 8 THE REPORTER: Do you want to read and  
 9 sign?  
 10 MS. MULLER: Yes.  
 11 MR. LABGOLD: In front of any Notary is  
 12 fine.  
 13

## EXAMINATION

## QUESTIONS BY MR. MARC R. LABGOLD:

14 Q Good morning, Dr. Liu.  
 15 A Good morning to you, too.  
 16 Q Have you ever been deposed before?  
 17 A No.  
 18 Q Okay. Just so you understand, I'm going to ask  
 19 you some questions, I'm going to show you some  
 20 documents. Hopefully my questions will be clear enough  
 21 that you'll understand.  
 22 If you don't understand the question, just  
 23 ask and I'll try to clarify.  
 24 Your counsel may have certain objections.  
 25

Page 5

1 She'll say, "Objection." The first time she does, I  
2 guarantee you you'll sit there and turn around and look  
3 at her and wait for something else. That's all it is,  
4 she's noting an objection for the record.  
5 Unless she instructs you not to answer,  
6 I'll expect an answer to the best of your ability.  
7 By whom are you currently employed?  
8 A U.T. Southwestern in Dallas.  
9 Q Okay. And what's your position there?  
10 A Post doctoral fellow.  
11 Q In whose lab?  
12 A Dr. Xiaodong Wang.  
13 Q And what type of work are you doing?  
14 A Biochemistry.  
15 Q On what type of project?  
16 A RNA Interference.  
17 Q And how long have you been in your current  
18 position?  
19 A Two years.  
20 Q And prior to that, am I correctly understanding  
21 you were at Baylor?  
22 A Yes.  
23 Q And for the entire time you were at Baylor,  
24 were you in Dr. Elledge's lab?  
25 A Yes.

Page 6

1 Q Now, did you prepare -- did you do anything to  
2 prepare for your deposition here today?  
3 A You mean the deposition document?  
4 Q Did you -- did you meet with your attorneys?  
5 A Yes.  
6 Q And who did you meet with?  
7 A I meet with Michelle and Tracy.  
8 Q Okay. And for how long did you meet?  
9 A About two --  
10 MS. MULLER: I'm going to object on the  
11 basis of privilege.  
12 MR. LABGOLD: That's not a privilege.  
13 You want me to show you transcripts from  
14 yesterday where I went through the same thing?  
15 It's not privileged that you met, it's not  
16 privileged where you met, it's not privileged how long  
17 you met. I'm allowed to ask him as I did for the last  
18 few depositions what documents he reviewed. I'm allowed  
19 to ask if anything refreshes his recollection.  
20 I can ask him what he discussed during  
21 those meetings and you can object and instruct him not  
22 to answer, but other than that, I'm entitled to an  
23 answer.  
24 Q (By Mr. Labgold) How long did you meet?  
25 MS. MULLER: Well, I'm going to have to

Page 7

1 review that, and if I'm incorrect on that, I will look  
2 at it, but for the moment I'm going to object on the  
3 basis of privilege.  
4 MR. LABGOLD: Well, it's not worth my  
5 time, but I will tell you this -- no.  
6 Q (By Mr. Labgold) Did you review any documents  
7 during your preparation?  
8 A No.  
9 Q Other than your meeting with your counsel at  
10 some unidentified undisclosed location -- the vice  
11 president may have been there with you but I won't ask  
12 that because that may also be privileged -- did you do  
13 anything else to prepare to be able to testify here  
14 today?  
15 A No.  
16 Q Have you spoken to Dr. Elledge anytime in the  
17 past year about the subject of the Univector System or  
18 this laboratory -- or this litigation?  
19 A Yes.  
20 Q And what were -- what did you discuss with Dr.  
21 Elledge?  
22 A I call him, ask him if he knows I have to talk  
23 to you, and he said he knew about it, it's fine.  
24 Q Did he tell you that he had had a deposition?  
25 A Yes.

Page 8

1 Q Did he tell you what questions were asked  
2 during that deposition?  
3 A No.  
4 Q Did you discuss anything else concerning the  
5 deposition or just asking him if it was okay to do a  
6 deposition?  
7 A He said, "Answer the question to your best  
8 knowledge, do not make any guess."  
9 Q Anything else?  
10 A No.  
11 Q Now, if I understand correctly, you were one of  
12 the people who contributed to the development of the  
13 Univector System, correct?  
14 A Yes.  
15 Q And you have prepared a paper which was  
16 published, disclosed in that system, correct?  
17 A Yes.  
18 Q And you also filed a patent application?  
19 A Yes.  
20 Q And is it my understanding -- is my  
21 understanding correct that it is you and Dr. Elledge  
22 that created the Univector System?  
23 A Yes.  
24 Q Now, I understand that Ms. Li was involved in  
25 a -- I don't know how best to describe it -- a variation

Page 9

1 of the Univector System where it was directed to  
2 homologous recombination. Is that your understanding?  
3 A It's all part of UPS system.  
4 Q Okay. And is that part of what was in your  
5 patent?  
6 A I don't know.  
7 Q Okay. Now, you collect royalties based on your  
8 contribution, correct?  
9 A Yes.  
10 Q And do you -- what frequency do you receive  
11 checks on that?  
12 A I don't remember.  
13 Q Do you recall how much you've received in  
14 total, approximately?  
15 A I can only estimate, but I'm not going to.  
16 Q Was it \$100,000?  
17 A Less than that.  
18 Q Was it \$50,000?  
19 A It's a couple of thousand dollars, I would say.  
20 Q Just like \$2,000?  
21 MS. MULLER: Objection; form.  
22 A I will say a couple of thousand dollars.  
23 Q (By Mr. Labgold) Okay. Well, I'm trying to get  
24 an idea of what you mean by "a couple."  
25 Colloquially in English, "a couple" would

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1 be two?  
2 A Oh, really?  
3 Q Some people would say "a few" is three, but we  
4 might differ on that.  
5 A Approximately \$5,000.  
6 Q And that's the total which you have received to  
7 the best of your understanding?  
8 A Per year.  
9 Q Per year. Okay.  
10 Were you involved in the decision of how  
11 the royalties would be distributed amongst you and your  
12 coinventors?  
13 A No.  
14 Q Let me mark as Lui Exhibit 1 a copy of a BCMT  
15 document bearing production number BCM 001659 through  
16 1664.  
17 (Exhibit No. 1 marked.)  
18 Q (By Mr. Labgold) If you take a look down at the  
19 document about halfway through the page, there's a  
20 heading there that says "Inventors."  
21 A Uh-huh.  
22 Q And then it gives a breakdown between you --  
23 Ms. Li and yourself.  
24 A Uh-huh.  
25 Q And does this comport with your collection

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1 that for 1999 you received approximately \$5,000?  
2 A You mean under the inventors, this part?  
3 Q Yeah.  
4 A Are you saying if the number looks correct?  
5 Q Yeah, your general collection?  
6 A Yes.  
7 Q Now, do you know why Ms. Li is not named as an  
8 inventor on the patent?  
9 A I don't know.  
10 MS. MULLER: Objection; form.  
11 Q (By Mr. Labgold) Was it your understanding that  
12 your contribution to the development of the Univector  
13 System and Ms. Li's were equivalent?  
14 MS. MULLER: Objection; form.  
15 A Can you rephrase the question?  
16 Q (By Mr. Labgold) Do you believe that Ms. Li  
17 contributed the same amount as you did to the  
18 development of the Univector System?  
19 MS. MULLER: Objection; form.  
20 A No.  
21 Q (By Mr. Labgold) Do you know why, then, Ms. Li  
22 obtains the same royalties as you do?  
23 A I don't know.  
24 Q Have you ever discussed that with Dr. Elledge?  
25 A No.

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1 Q Have you ever discussed that with anybody else  
2 at Baylor or BCMT?  
3 A Yes.  
4 THE WITNESS: Is that a privilege?  
5 MS. MULLER: To the extent that you spoke  
6 with counsel or involved communication of counsel, then  
7 I instruct you not to answer.  
8 A That involves discussion with patent counsel at  
9 Baylor.  
10 Q (By Mr. Labgold) Well, at any time did you  
11 raise a concern with anyone at BCMT as to whether the  
12 distribution of royalties was equitable?  
13 MS. MULLER: Again, to the extent that  
14 that requires you to discuss -- to disclose any  
15 conversation with counsel, I instruct you not to answer.  
16 MR. LABGOLD: And Counsel, I would -- I  
17 don't have the energy or the time to deal with this. I  
18 will just note on the record -- and I can tell we're  
19 coming back for another deposition, and it's going to be  
20 on your client's dime.  
21 Because if he's going to Baylor and he's  
22 complaining or inquiring as to why his amount is  
23 equivalent to somebody who joined the project after the  
24 patent was filed, that's not a king legal counsel.  
25 That's a business dispute.

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1 Now, you can instruct him as you will.  
 2 I'll give you a moment to think about it. If you're  
 3 going to tell me the instruction stands, I'll move on,  
 4 and we'll deal with that later.  
 5 MS. MULLER: For the moment the  
 6 instruction stands.  
 7 MR. LABGOLD: Okay.  
 8 Q (By Mr. Labgold) Did you ever get an answer as  
 9 to why Ms. Li gets the same amount of royalties as you  
 10 do despite --  
 11 A No.  
 12 Q -- the fact that --  
 13 Fair enough.  
 14 I'd like to mark as Liu Exhibit 2 a copy  
 15 of an affidavit which you signed.  
 16 (Exhibit No. 2 marked.)  
 17 Q (By Mr. Labgold) Can you tell me if you've seen  
 18 this document before today?  
 19 A Yes.  
 20 Q Did you yourself prepare the text of the  
 21 document?  
 22 A Yes.  
 23 Q Did you type it yourself?  
 24 A No.  
 25 Q So if I understand correctly, you wrote the

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1 text of the document and then forwarded it to somebody  
 2 else for typing?  
 3 MS. MULLER: Objection; privileged.  
 4 To the extent that that requires you to  
 5 reveal any conversation you had with counsel, again --  
 6 MR. LABGOLD: There is nothing privileged  
 7 about that. I am entitled to know how he prepared his  
 8 declaration, affidavit, whatever you want to call it,  
 9 his sworn statement.  
 10 Q (By Mr. Labgold) Are you going to --  
 11 MS. MULLER: If it involved a conversation  
 12 with counsel, I'm going to instruct him not to answer.  
 13 MR. LABGOLD: Have you done this before?  
 14 MS. MULLER: Sir?  
 15 MR. LABGOLD: Have you done this before?  
 16 MS. MULLER: I'm not being deposed here.  
 17 Q (By Mr. Labgold) When you signed this  
 18 affidavit, did you understand that you were under oath?  
 19 A Yes.  
 20 Q Did you understand what the consequences were  
 21 if you made a statement which were not true, to your  
 22 knowledge, in a sworn statement?  
 23 A Yes.  
 24 Q And do you understand that you are under oath  
 25 heretoday, and that if you do not tell the truth, that

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1 the penalty of perjury adheres to that?  
 2 A Yes.  
 3 Q Okay. If you take a look at Paragraph 2 under  
 4 Roman numeral two, says: (Reading) I contributed to the  
 5 development of the univector plasmid-fusion system.  
 6 What was your contribution?  
 7 A My contributions to develop the Cre enzyme and  
 8 show this concept, this system works in principle.  
 9 Q When you say "develop the Cre enzyme," what are  
 10 you talking about?  
 11 A Making the GST-Cre.  
 12 Q So making a GST-Cre fusion, correct?  
 13 A No.  
 14 Q Please explain.  
 15 A Not only that, more than that.  
 16 Q Okay. Please explain.  
 17 A Making the --  
 18 MS. MULLER: Objection; form. I'm sorry.  
 19 Go ahead.  
 20 A Making a fusion protein, express it, an E.  
 21 coli, purify it, demonstrate the purified protein has  
 22 high -- high specific activity.  
 23 Q (By Mr. Labgold) Okay. Now, GST fusion  
 24 proteins were known in the art prior to your work,  
 25 correct?

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1 A Correct.  
 2 Q And the Cre enzyme itself was known in the art  
 3 prior to your work, correct?  
 4 A Correct.  
 5 Q And am I correct in understanding that the Cre  
 6 recombinase, the Cre enzyme, its ability to recombine  
 7 loxP site was also known in the art, correct?  
 8 A Correct.  
 9 Q If you take a look at page -- I'm sorry, we got  
 10 a stapling error here.  
 11 Actually, looking at Page 2 of your  
 12 declaration, and you say that the Univector System was  
 13 described and explained in an article and then it sets  
 14 forth the article. Do you see that?  
 15 A Uh-huh, the first two sentences.  
 16 Q Yes. And I'd like to mark -- let me give you a  
 17 document we've already marked as Elledge Exhibit 3, if  
 18 you can confirm for me that is the article to which you  
 19 were referring?  
 20 A Yes.  
 21 Q And when you prepared -- let me ask this: Were  
 22 you involved in the preparation of the article?  
 23 A Yes.  
 24 Q And to the best of your ability, did you  
 25 completely and fully describe the Univector System in

## CERTIFICATE OF SERVICE

I hereby certify that on May 20, 2003 I caused to be delivered by fax and FED EX a copy of **PROTEST AGAINST PENDING APPLICATION UNDER 37 C.F.R. § 1.291** and exhibits 1-8 thereto relating to USSN 09/122,384, addressed to the attorney of record in that matter as follows:

Timothy S. Corder  
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Austin, Texas 78746-7568  
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I declare under penalty of perjury that the foregoing is true and correct.

A handwritten signature in black ink, appearing to read "Timothy S. Corder", written over a horizontal line.